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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION	Lead Case No. 3:21-CV-03825-VC
THIS DOCUMENT RELATES TO: ALL ACTIONS	DEFENDANT INTUITIVE SURGICAL, INC.'S ANSWER AND AFFIRMATIVE DEFENSE Judge: The Honorable Vince Chhabria Amended Complaint Filed: September 10, 2021

DEFENDANT’S ANSWER AND AFFIRMATIVE DEFENSE

Defendant Intuitive Surgical, Inc. (“Intuitive”) hereby sets forth its Answer and Affirmative Defense to the Consolidated Amended Complaint (ECF No. 52, “Complaint”) filed by Plaintiffs Larkin Community Hospital, Franciscan Alliance, Inc., King County Public Hospital District No. 1, DBA Valley Medical Center, and Kaleida Health (collectively, “Plaintiffs”). Except as otherwise expressly set forth below, Intuitive denies knowledge or information sufficient to form a belief as to the truth or falsity of each and every allegation contained in the Complaint. Any allegation, averment, contention or statement in the Complaint not specifically and unequivocally admitted is denied, including any statement in a heading. Intuitive preserves all objections regarding the admissibility of any allegations or statements made in the Complaint or in this Answer and Affirmative Defense. Intuitive responds to each of the paragraphs of the Complaint as follows:

RESPONSE TO “INTRODUCTION”

Paragraph 1: Intuitive dominates the market for minimally invasive surgical robots with its da Vinci robots (“da Vinci”). Intuitive’s dominance in this market is so complete that for over a decade Intuitive faced no competition whatsoever. Even now, Intuitive maintains a market share of at least 98%. Through anticompetitive conduct, Intuitive abuses its dominance to limit competition two separate markets: (1) the aftermarket for da Vinci service; and (2) the aftermarket for the replacement and repair of EndoWrists, i.e., the costly, limited-use surgical instruments (such as graspers, forceps, and scissors) required to perform surgery with a da Vinci.

1. Intuitive denies the allegations in paragraph 1.

Paragraph 2: Intuitive has been engaged in an anticompetitive scheme pursuant to which it ties the purchase or lease of the da Vinci to, and otherwise conditions the purchase or lease of the da Vinci on, the purchase from Intuitive of service of the da Vinci and the repair and replacement of EndoWrists—a violation of Sections 1 and 2 of the Sherman Act.

2. Intuitive denies the allegations in paragraph 2.

Paragraph 3: Intuitive conditions the purchase or lease of a da Vinci on acceptance of Intuitive’s service contract. The service contract requires the purchaser to use Intuitive as the sole service provider for all da Vincis and prohibits the purchaser from either servicing the robot itself or hiring an independent repair company (“IRC”) to service the da Vinci.

3. Intuitive admits that customers enter into a “Sales, License and Service

Agreement” (“SLSA”) with Intuitive when they purchase or lease a da Vinci Surgical System (“da Vinci”) and that through the SLSA, customers have the option to enter into a service contract with Intuitive, but otherwise denies the allegations in the first sentence of paragraph 3. Intuitive admits that the SLSA prohibits customers from engaging any unauthorized third party to service the da Vinci, but otherwise denies the allegations in the second sentence of paragraph 3.

Paragraph 4: Intuitive also ties the purchase or lease of a da Vinci to the purchase of replacement EndoWrists from Intuitive. Both contractually and technologically, Intuitive restricts the number of times a purchaser may use the EndoWrists, in most cases to a mere ten uses—without any medical justification. The sole purpose of artificially suppressing the number of EndoWrist uses is to artificially inflate the number of EndoWrists hospitals must purchase to perform life-saving surgeries. Moreover, according to the terms of the agreements Intuitive requires for the purchase or lease of the da Vinci (“Sales Agreements”), hospitals cannot hire IRCs to service or repair their EndoWrists (e.g., clean or sharpen them for longer use). These restrictions cause Plaintiffs and proposed Class members (defined in paragraph 163, *infra*; hereinafter, the “Class”)) to purchase at supracompetitive prices substantially more EndoWrists than necessary.

4. Intuitive denies the allegations in the first, second, third and fifth sentences of paragraph 4. Intuitive admits that the SLSA prohibits customers from engaging any unauthorized third party to repair, refurbish, or recondition instruments, including instruments with EndoWrist technology (“EndoWrists”), at any time, but otherwise denies the allegations in the fourth sentence of paragraph 4.

Paragraph 5: Intuitive’s conduct with regard to both da Vinci service and EndoWrist repair and replacement is precisely the type of anticompetitive behavior the Federal Trade Commission (“FTC”) condemned in a July 2021 Policy Statement, in which the FTC explained that as part of its “Nixing the Fix” workshop, “the Commission uncovered evidence that manufacturers and sellers may, without reasonable justification, be restricting competition for repair services in numerous ways, including . . . limiting the availability of parts, manuals, diagnostic software, and tools . . . disparaging non-OEM parts and independent repair; using unjustified software locks . . . and imposing restrictive end use license agreements.”¹ The FTC specifically noted that “certain repair restrictions may constitute tying arrangements or monopolistic practices—such as refusals to deal, exclusive dealing, or exclusionary design—that violate the Sherman Act.”²

Footnote 1: Policy Statement of the Federal Trade Commission on Repair Restrictions Imposed by Manufacturers and Sellers (July 21, 2021), at 1, available at https://www.ftc.gov/system/files/documents/public_statements/1592330/p194400repairrestrictio

nspolicystatement.pdf (last visited on September 10, 2021).

Footnote 2: *Id.* at 2.

5. Intuitive denies the allegations in paragraph 5, except states that to the extent paragraph 5 purports to characterize and quote from a July 21, 2021 Federal Trade Commission report, Intuitive respectfully refers to that article for its full context and contents.

Paragraph 6: There is a relevant primary market for minimally invasive surgical robots, and relevant aftermarkets for the (a) service of da Vinci robots and (b) repair and replacement of EndoWrists, which are separate from the primary market and from each other. Intuitive has monopoly power in every relevant primary market and aftermarket. Intuitive illegally exploits its market power in the minimally invasive surgical robot market to foreclose competition in the aftermarkets for da Vinci service and the repair and replacement of EndoWrists. The scheme is highly successful and has almost completely inhibited competition in those aftermarkets, precluding customers from using IRCs, which deliver the same quality service at lower prices. Intuitive's conduct has thereby significantly increased costs to Plaintiffs and the Class. For example, IRCs Restore Robotics LLC ("Restore"), Surgical Instrument Service Company, Inc. ("SIS"), Revanix Biomedical ("Revanix"), and Rebotix Repair LLC ("Rebotix") offer repair services for EndoWrists by skilled and experienced technicians and Restore likewise services the da Vinci itself. Other companies are in the business of servicing and repairing medical equipment and/or surgical instruments and would likely enter the aftermarkets for servicing of da Vinci robots and/or repairing and replacing EndoWrists but for Intuitive's anticompetitive conduct.

6. Intuitive denies the allegations in paragraph 6.

Paragraph 7: Defendant's anticompetitive scheme drives the majority of its annual revenues: in 2019, 57% of Intuitive's U.S. revenue was attributable to instrument and accessory sales and replacement, and 16% was attributable to service contracts.

7. Intuitive admits that in its 10-K for the year ended December 31, 2019, Intuitive reported total United States revenues of approximately \$3.13 billion, of which approximately 16% was attributable to service and approximately 57% was attributable to sales of instruments and accessories, but otherwise denies the allegations in paragraph 7.

Paragraph 8: But for Intuitive's anticompetitive scheme, IRCs could service the da Vinci and EndoWrists, which would allow for competitive pricing in the da Vinci service and EndoWrist repair and replacement aftermarkets. For example, SIS states that it charges its customers approximately 30-45% less to clean or repair an EndoWrist than Intuitive charges to replace the same EndoWrist. Restore similarly estimates that Intuitive charges at least 25% higher prices on average for EndoWrist replacement as compared to EndoWrist repairs performed by IRCs. Denying IRCs the ability to service da Vincis causes Plaintiffs and Class members, such as

hospitals and clinics, to pay supracompetitive prices for these services. Likewise, denying IRCs the ability to repair EndoWrists causes Plaintiffs and the Class continually to spend thousands of dollars replacing instruments that could be repaired and safely reused throughout those instruments' useful lives.

8. Intuitive denies the allegations in the first, fourth and fifth sentences of paragraph 8. Intuitive admits that SIS and Restore make representations to customers about the pricing of their "repair" service and its comparison to the price of EndoWrists, but otherwise denies the allegations in the second and third sentences of paragraph 8 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 9: Plaintiffs bring this action on behalf of themselves and a Class of similarly situated direct purchasers to put an end to Intuitive's anticompetitive conduct and remedy the injuries it has caused.

9. Intuitive admits that Plaintiffs have brought a lawsuit on behalf of themselves and a purported Class, but otherwise denies the allegations in paragraph 9.

RESPONSE TO "PARTIES"

Paragraph 10: Plaintiff Larkin Community Hospital ("Larkin") is a Florida corporation with its principal place of business located in Miami, Florida.

10. Intuitive denies the allegations in paragraph 10 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 11: Larkin leased two da Vincis, an Xi and an Si, from Defendant Intuitive in June 2017, pursuant to written lease agreements. During the proposed Class Period (defined in paragraph 163, *infra*), Larkin paid for and/or purchased (a) service for its da Vincis, and (b) replacement EndoWrists.

11. Intuitive admits that Larkin leased a da Vinci Xi and a da Vinci Si from Intuitive in June 2017 and signed written lease agreements for those da Vincis. Intuitive otherwise denies the allegations in paragraph 11 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 12: In 2018, to save significant costs on its EndoWrist service and replacements, Larkin engaged Revanix, an IRC it had used before in connection with the service and repair of

other types of medical equipment. Larkin was confident that Revanix could adequately service its EndoWrists at significant cost savings to Larkin. However, before Larkin could hire Revanix, Intuitive threatened to serve Larkin (and Revanix) with cease-and-desist letters and void the warranty on Larkin's da Vincis. Based on those threats, Larkin stopped its efforts to have Revanix service its EndoWrists.

12. Intuitive denies the allegations in paragraph 12 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 13: The agreements associated with Larkins's da Vinci leases required that Larkin use Intuitive as its exclusive servicer for any maintenance of its da Vincis, and that Larkin purchase replacement EndoWrists according to Intuitive's arbitrary use limits. As a result, during the Class Period, for each of its da Vincis, Larkin has regularly paid for and/or purchased from Intuitive (a) maintenance services at supracompetitive prices, and (b) unnecessary replacement EndoWrists. Larkin spent substantially more on da Vinci service and replacement EndoWrists than it would have absent Intuitive's anticompetitive conduct.

13. Intuitive admits that the SLSA between Intuitive and Larkin prohibits Larkin from engaging any unauthorized third party to service its da Vincis and from engaging any unauthorized third party to repair, refurbish, or recondition EndoWrists at any time, but otherwise denies the allegations in the first sentence of paragraph 13. Intuitive denies the allegations in the second and third sentences of paragraph 13.

Paragraph 14: Plaintiff Franciscan Alliance, Inc. operates a not-for-profit healthcare system, known as Franciscan Health, Inc. (collectively, "Franciscan"). Franciscan is one of the largest Catholic healthcare systems in the Midwest, with 13 hospital campuses that serve patients in Indiana, Illinois, and Michigan. During the proposed Class Period, Franciscan paid for and/or purchased (a) service for its da Vincis, and (b) replacement EndoWrists.

14. Intuitive denies the allegations in paragraph 14 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 15: Franciscan has offered minimally invasive robotic surgery to its patients for over a decade, and multiple Franciscan campuses have da Vincis. Once [sic] such campus, Franciscan Health Crown Point, in Crown Point, Indiana, first purchased a da Vinci in 2010. Franciscan Health Michigan City, in Michigan City, Indiana, has owned and operated a da Vinci since 2010. And Franciscan Health Dyer, in Dyer, Indiana, has owned and operated a da Vinci since 2012.

15. Intuitive denies the allegations in paragraph 15 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 16: At these and other Franciscan campuses, surgeons regularly use da Vincis to perform minimally invasive robotic surgeries. Surgeons at Franciscan Health Indianapolis, for example, performed 455 da Vinci procedures in 2017 alone. Franciscan surgeons use the da Vinci for a variety of surgeries, including general, gynecologic, colorectal, thoracic, and urologic procedures.

16. Intuitive denies the allegations in paragraph 16 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 17: The agreements associated with Franciscan's purchase of these da Vincis required that Franciscan use Intuitive as its exclusive servicer for any maintenance of its da Vincis, and that Franciscan purchase replacement EndoWrists according to Intuitive's arbitrary use limits. As a result, during the proposed Class Period, for each of its da Vincis, Franciscan has regularly paid for and/or purchased from Intuitive (a) da Vinci maintenance services at supracompetitive prices, and (b) unnecessary replacement EndoWrists. Franciscan spent substantially more on da Vinci service and replacement EndoWrists than it would have absent Intuitive's anticompetitive conduct.

17. Intuitive admits that the SLSA between Intuitive and Franciscan prohibits Franciscan from engaging any unauthorized third party to service its da Vincis and from engaging any unauthorized third party to repair, refurbish, or recondition EndoWrists at any time, but otherwise denies the allegations in the first sentence of paragraph 17. Intuitive denies the allegations in the second and third sentences of paragraph 17.

Paragraph 18: Plaintiff King County Public Hospital District No. 1, DBA Valley Medical Center ("Valley Medical"), is a Washington municipal corporation and nonprofit healthcare provider located in Renton, Washington. Valley Medical is the largest nonprofit healthcare provider between Seattle and Tacoma, serving over 600,000 residents. Valley Medical is managed as a component of University of Washington Medicine, subject to the oversight of a Board of Trustees, and includes a hospital and a network of more than 40 primary and specialty care clinics throughout Southeast King County, Washington. During the proposed Class Period, Valley Medical paid for and/or purchased (a) service for its da Vincis, and (b) replacement EndoWrists.

18. Intuitive denies the allegations in paragraph 18 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 19: Valley Medical has used da Vincis, including the Si and Xi, since 2006 at the latest. Today, Valley Medical owns two Xi models, which Valley Medical uses for surgeries and conditions including hysterectomy, fibroid tumor, gynecologic cancer, and other gynecologic surgery. Over the last several years, Valley Medical has averaged nearly 350 surgeries annually

using da Vincis. That number has increased in recent years, reaching 430 such surgeries in 2019 alone.

19. Intuitive denies the allegations in paragraph 19 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 20: The agreements associated with Valley Medical's purchase of these da Vincis require that Valley Medical use Intuitive as its exclusive servicer for any maintenance of its da Vincis, and that Valley Medical purchase replacement EndoWrists according to Intuitive's arbitrary use limits. As a result, during the proposed Class Period, for each of its da Vincis, Valley Medical regularly paid for and/or purchased from Intuitive (a) da Vinci maintenance services at supracompetitive prices, and (b) unnecessary replacement EndoWrists. Valley Medical spent substantially more on da Vinci service and replacement EndoWrists than it would have absent Intuitive's anticompetitive conduct.

20. Intuitive admits that the SLISA between Intuitive and Valley Medical prohibits Valley Medical from engaging any unauthorized third party to service its da Vincis and from engaging any unauthorized third party to repair, refurbish, or recondition EndoWrists at any time, but otherwise denies the allegations in the first sentence of paragraph 20. Intuitive denies the allegations in the second and third sentences of paragraph 20.

Paragraph 21: Plaintiff Kaleida Health is a New York not-for-profit corporation with its principal place of business in Buffalo, New York. During the proposed Class Period, Kaleida leased and/or purchased da Vinci Xi models including, without limitation, da Vinci Xi, X, and Si models directly from Defendant Intuitive, pursuant to written agreements, and paid Defendant Intuitive for service to its da Vincis and replacement EndoWrists.

21. Intuitive denies the allegations in paragraph 21 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 22: As a result of Intuitive's antitrust violations, Plaintiffs and members of the Class have been injured in their business or property.

22. Intuitive denies the allegations in paragraph 22.

Paragraph 23: Defendant Intuitive Surgical, Inc. is a Delaware corporation with its principal place of business at 1020 Kifer Road, Sunnyvale, CA. Intuitive manufactures the da Vinci. Intuitive also manufactures and sells EndoWrists and other accessories used with the da Vinci. Intuitive directly sells da Vincis and EndoWrists, and associated parts and services, to hospitals, clinics, and surgical centers throughout the United States, including in the Northern District of California.

23. Intuitive admits that it is a Delaware corporation with its executive offices at 1020 Kifer Road, Sunnyvale, California, but otherwise denies the allegations in first sentence of paragraph 23. Intuitive admits the allegations in the second and third sentences of paragraph 23.

RESPONSE TO “VENUE AND JURISDICTION”

Paragraph 24: This complaint is filed under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. This Court has jurisdiction over the federal antitrust law claims alleged herein under 28 U.S.C. §§ 1331, 1337, 2201 and 2202, and 15 U.S.C. §§ 15 and 26.

24. Intuitive admits that the Complaint purports to assert claims under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2.

Paragraph 25: Defendant transacts business and is found in this district. Substantial interstate trade and commerce involved and affected by the alleged violations of antitrust law occurs within this district. The acts complained of have had substantial anticompetitive effects in this district. Venue is proper in this district under 28 U.S.C. § 1391 and 15 U.S.C. §§ 15, 22, and 26.

25. Intuitive admits that it transacts business and is located in this district and that venue is proper in this district under 28 U.S.C. § 1391 and 15 U.S.C. §§ 15, 22, and 26, but otherwise denies the allegations in paragraph 25.

RESPONSE TO “A. RELEVANT MARKETS AND INTUITIVE’S ANTICOMPETITIVE CONDUCT”

Paragraph 26: Minimally invasive surgical robots are used for soft tissue surgeries performed between the pelvis and the head. Minimally invasive robotic surgery, like laparoscopic surgery done by hand, makes several small incisions in soft tissue for the insertion of small surgical instruments to perform a surgical procedure. The surgeon, sitting at a computer, uses hand-controls to manipulate the instruments, which are attached to the da Vinci by robotic arms with joints.

26. Intuitive admits that robotic-assisted surgery can be used to perform soft tissue surgeries between the pelvis and the head, but otherwise denies the allegations in the first sentence of paragraph 26. Intuitive admits that surgery performed with the da Vinci involves small incisions in soft tissue for the insertion of small tools like in laparoscopic surgery, but otherwise denies the allegations in the second sentence of paragraph 26 because it is without

knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Intuitive admits that surgery performed with the da Vinci involves a surgeon sitting at the surgeon's console and using hand controls to manipulate the instruments, which are attached to the system by robotic arms with joints, but otherwise denies the allegations in the third sentence of paragraph 26.

Paragraph 27: Minimally invasive robotic surgeries largely mirror laparoscopic surgeries that have been performed by hand for decades, but differ in a number of respects, including:

- i. Stereoscopic high-definition cameras for 3-D visibility;
- ii. An additional robotic arm, which allows the simultaneous use of three instruments;
- iii. Wrist joints that allow for an expanded range of motion compared to human mobility;
- iv. The ability to precisely perform small, discrete movements with the robotic arms and instruments;
- v. Minimizing surgeon fatigue; and
- vi. According to Intuitive, decreasing complication rates and reducing the lengths of patient stays.

27. Intuitive admits that the da Vinci may provide surgeons using the system with enhanced visualization, dexterity, precision, that the da Vinci has more “arms” than a human and that it may minimize surgeon fatigue. Intuitive also admits that da Vinci surgeries may offer lower complications rates and reduce the lengths of patient stays than alternative healthcare options for certain procedures. Intuitive otherwise denies the allegations in paragraph 27 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 28: There is a relevant product market for minimally invasive surgical robots. Surgical robots have no practical substitute, because although robotic surgery is significantly more expensive and less profitable than traditional laparoscopic surgical procedures, hospitals are expected to offer robotic surgeries.

28. Intuitive denies the allegations in paragraph 28.

Paragraph 29: In fact, the very characteristics that make minimally invasive surgical robots

unique and more expensive — enhanced visualization using high-definition cameras, precise and tremor-free instrument controls, advanced instrumentality, and improved surgeon ergonomics — make minimally invasive robotic surgeries preferable to traditional laparoscopic procedures for many surgeons. Notwithstanding the fact that minimally invasive robotic surgery is itself more expensive than traditional laparoscopic surgery, many hospitals believe that minimally invasive robotic surgery can lower the overall cost to treat per episode by reducing complications, shortening recovery times and hospital stays, and resulting in better long-term health outcomes and higher patient satisfaction than with traditional laparoscopic surgery. Many patients believe minimally invasive robotic surgery will reduce pain and scarring, and regard it as safer and more effective than traditional laparoscopic surgeries. Thus, minimally invasive robotic surgery is in many cases preferable for hospitals and their surgeons and patients.

29. Intuitive denies the allegations in paragraph 29 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 30: The market for minimally invasive surgical robots is a distinct market. For example, although traditional laparoscopic surgeries are far cheaper than robotic alternatives and their outcomes have been reported to be largely equivalent, Intuitive has successfully promoted minimally invasive robotic surgery as a superior alternative to traditional laparoscopic surgery. With patients and doctors demanding robotic options, hospitals are compelled either to offer them or to forego significant business. Intuitive claims that minimally invasive robotic surgeries provide several advantages for surgeons over traditional laparoscopic surgeries, including increased dexterity, improved hand-eye coordination and ergonomic position, and improved visualization. The robot has more “arms” than a human, which allows the surgeon to hold additional instruments. The “wrists” of the robot have a greater range of motion than a human wrist, which allows for greater dexterity. The movements of the instruments can be scaled relative to the movements of the controller, which allows for greater precision. The console from which the surgeon operates is designed to minimize surgeon fatigue.

30. Intuitive denies the allegations in the first and second sentences of paragraph 30. Intuitive denies the allegations in the third sentence of paragraph 30 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive admits that it has stated that the da Vinci may provide advantages for surgeons using the system with enhanced visualization, dexterity, precision and ergonomics, that the da Vinci has more “arms” than a human, that EndoWrists can achieve a greater range of motion than a human hand, that the movements of a surgeon using the da Vinci are scaled, filtered and translated to the system’s instruments and that the da Vinci may reduce fatigue during surgical procedures, but otherwise denies the allegations in the fourth, fifth, sixth, seventh and eighth sentences of

paragraph 30.

Paragraph 31: Because of the distinct attributes of surgical robots and Intuitive’s aggressive promotion of the da Vinci, many doctors and patients believe minimally invasive robotic surgeries are superior to traditional laparoscopic surgeries. Intuitive advertises that da Vinci surgeries provide patients with “improved outcomes” and “fewer complications” and that a hospital that lacks a da Vinci will provide patients with worse outcomes and more complications.

31. Intuitive denies the allegations in the first sentence of paragraph 31 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive admits that there is medical literature that supports the claim that minimally invasive robotic surgeries may offer improved outcomes and fewer complications than alternative healthcare options for certain procedures, but otherwise denies the second sentence of paragraph 31.

Paragraph 32: Many doctors prefer to perform—and indeed only have the skills to perform—minimally invasive robotic surgeries and not traditional laparoscopic surgeries. They learned how to perform minimally invasive robotic surgeries (in particular, da Vinci surgeries) in medical school, and they have been performing only da Vinci surgeries for years. These doctors will work only at hospitals that have da Vincis.

32. Intuitive denies the allegations in paragraph 32 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 33: Intuitive and many hospitals promote the distinction between da Vinci surgeries and traditional surgeries. They emphasize the alleged superiority of da Vinci surgeries. Intuitive states that “100% of the top-ranked U.S. hospitals for cancer, urology, gynecology and gastroenterology diseases all use da Vinci surgical systems.”

33. Intuitive denies the allegations in the first and second sentences of paragraph 33 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive admits that it has stated that “100% of the top-ranked U.S. hospitals for cancer, urology, gynecology and gastroenterology diseases all use da Vinci Surgical Systems,” but otherwise denies the allegations in the third sentence of paragraph 33.

Paragraph 34: There is very little if any cross-elasticity of demand between surgical robots and laparoscopic surgery equipment, instruments, and service. A 2017 study estimated that the per-

surgery cost to a hospital of purchasing and maintaining the da Vinci averaged \$1,701, and that hospitals spent an additional \$1,866 per procedure, on average, for the instruments and accessories used in a robotic surgery.³ In traditional laparoscopic surgeries, in contrast, the marginal cost of reusable instruments is less than a few hundred dollars per surgery, and disposable instruments typically cost less than \$1,000.⁴ Further, most insurance plans pay the same amount for minimally invasive robotic surgery as for the equivalent laparoscopic surgery, such that patients pay much more out of pocket for minimally invasive robotic surgery and hospitals have lower (and sometimes negative) margins on the procedures. Nevertheless, according to Intuitive, the number of robotic surgeries performed increased from 136,000 in 2008⁵ to an estimated 1,243,000 in 2020.⁶ Intuitive boasts that a surgeon starts a procedure using a da Vinci surgical robot every 25.4 seconds. Thus, it is apparent that an increase in the cost of a minimally invasive surgical robot, instruments, and service does not lead doctors or patients to choose laparoscopic or traditional surgery instead, nor would a change in the cost of traditional or laparoscopic equipment impact the doctors or patients opting for minimally invasive robotic surgery. Put another way, a hypothetical monopolist of minimally invasive surgical robots could impose a small but significant, non-transitory increase in price without losing meaningful market share to alternative products or services, such as those involved in laparoscopic surgery. Indeed, Intuitive has done just that in the real world, charging substantial premiums over laparoscopic alternatives without losing sales or revenue streams, but instead steadily increasing its sales over time.

Footnote 3: Christopher P. Childers and Melinda Maggard-Gibbons, Research Letter: Estimation of the Acquisition and Operating Costs for Robotic Surgery, 320 Journal of American Medical Association 835, 836 (August 28, 2018).

Footnote 4: *Id.*

Footnote 5: Intuitive (Form 10-K), at 4 (Feb. 6, 2009).

Footnote 6: Intuitive (Form 8-K), at 1 (Jan. 13, 2021).

34. Intuitive denies the allegations in the first, seventh, eighth and ninth sentences of paragraph 34. Intuitive denies the allegations in second and third sentences of paragraph 34, except states that to the extent that the second and third sentences of paragraph 34 purport to characterize and quote from an August 28, 2018 Journal of American Medical Association article, Intuitive respectfully refers to that article for its full context and contents. Intuitive denies the allegations in the fourth sentence of paragraph 34 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive admits that in its 10-K for the year ended December 31, 2009, Intuitive reported that approximately 136,000 surgical procedures were performed with da Vincis and that in its 8-K dated January 13, 2021, Intuitive reported that in 2020, approximately 1,243,000 surgical procedures were

performed with da Vincis, but otherwise denies the allegations in the fifth sentence of paragraph 34. Intuitive admits that, on its website, it has stated that a surgeon starts a procedure using a da Vinci every 25.4 seconds, but otherwise denies the allegations in the sixth sentence of paragraph 34.

Paragraph 35: Likewise, instead of shifting to cheaper laparoscopic equipment for surgeries, hospitals are investing millions in minimally invasive surgical robots, even at much higher prices. Accordingly, neither laparoscopic instruments nor any other devices are substitutable with minimally invasive surgical robots, as hospitals will not switch to those instruments or devices even if the price of minimally invasive robots is raised above competitive levels (as it is for the da Vinci, as well as related service and EndoWrists).

35. Intuitive denies the allegations in the first sentence of paragraph 35 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the second sentence of paragraph 35.

Paragraph 36: Minimally invasive surgical robots and traditional laparoscopic surgical equipment occupy separate economic markets. The financial and healthcare press refer specifically to the market for surgical robots and competition in surgical robots. Surgeons can specialize in robotic surgery, and there are several professional and trade associations focused on robotic surgery such as the Society for Robotic Surgery and the Clinical Robotic Surgery Association. Moreover, most manufacturers that make surgical robots specialize in surgical robots. They do not also make equipment for traditional laparoscopic surgeries.

36. Intuitive denies the allegations in the first sentence of paragraph 36. Intuitive denies the allegations in the second, third, fourth and fifth sentences of paragraph 36 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 37: Founded in 1995, Intuitive designs and manufactures the da Vinci, and markets it directly to its customers in the U.S. The Food and Drug Administration (“FDA”) approved the da Vinci for general laparoscopic surgery in 2000.⁷ It is approved for both adult and pediatric use.

Footnote 7: Intuitive (Form 10-K), at 5 (Feb. 10, 2021).

37. Intuitive admits the allegations in paragraph 37.

Paragraph 38: The da Vinci, pictured below in Figure 1, consists of three main components: the surgeon’s console, where the surgeon sits to perform the operation; the patient-side cart, which

holds the camera and surgical instruments controlled by the surgeon; and the vision system, which includes a view screen that allows the care team to view the surgery in real time.⁸

Footnote 8: *Id.* at 6.

Figure 1: the da Vinci with attached EndoWrists
[IMAGE]

38. Intuitive admits that the da Vinci includes the surgeon's console, where the surgeons sits to perform the operation, the patient-side cart that holds electromechanical arms that manipulate the instruments inside the patient and the vision system that allows the surgical team to view the surgery, but otherwise denies the allegations in paragraph 38, except states that to the extent paragraph 38 further characterizes Intuitive's 10-K for the fiscal year ended on December 31, 2020, Intuitive respectfully refers to that filing for its full context and contents.

Paragraph 39: There are four generations of Intuitive da Vincis: the latest generation includes the Xi, X, and SP models. The third generation is the Si model; the second is the S model; and the first-generation is the "standard" model. The da Vinci SP is the latest model to be launched, in 2018.⁹ As discussed below, the da Vinci X and Xi models use different EndoWrists than earlier models.

Footnote 9: *Id.* at 63

39. Intuitive admits that it has developed and sold different generations of da Vincis, including the da Vinci S, da Vinci Si, da Vinci Xi, da Vinci X and da Vinci SP. Intuitive admits that its da Vinci SP model, launched in 2018, is currently the most recent model. To the extent the third sentence of paragraph 39 further characterizes Intuitive's 10-K for the fiscal year ended on December 31, 2020, Intuitive respectfully refers to that filing for its full context and contents. Intuitive admits that EndoWrists designed for use with the da Vinci X and Xi models are different from EndoWrists designed for the S and Si models. Intuitive otherwise denies the allegations in paragraph 39.

Paragraph 40: Intuitive sells the da Vinci directly to hospitals and surgical centers, and also enters lease arrangements directly with certain qualified customers, a practice it started in 2013.¹⁰ It also has entered use-based arrangements with larger customers. Under such arrangements, hospitals are charged for the robot and service as they are utilized.

Footnote 10: *Id.* at 56

40. Intuitive admits that it sells da Vincis directly to hospitals and surgical centers. Intuitive admits that in its 10-K for the year ended December 31, 2020, Intuitive stated that since 2013, Intuitive has “entered into sales-type and operating lease arrangements directly with certain qualified customers.” Intuitive denies the remaining allegations in first sentence of paragraph 40, except states that to the extent paragraph 40 further characterizes and quotes from Intuitive’s 10-K for the fiscal year ended on December 31, 2020, Intuitive respectfully refers to that filing for its full context and contents. Intuitive admits that in its 10-K for the year ended December 31, 2020, Intuitive stated that since 2013, Intuitive has “entered into usage-based arrangements with larger customers that have committed da Vinci programs where [Intuitive] charge[s] for the system and service as the systems are utilized,” but otherwise denies the allegations in the second sentence of paragraph 40.

Paragraph 41: As of December 31, 2020, Intuitive had an installed base of 3,720 da Vincis in the U.S.¹¹ The U.S. installed base has increased over 45% in the past four years alone: as of December 31, 2016, Intuitive had an installed base of 2,563 da Vincis in the U.S.¹² Moreover, despite the coronavirus pandemic, the U.S. installed base grew more than 5% in 2020.¹³ Intuitive maintains a market share of at least 98% of the minimally invasive surgical robot market and holds similarly high shares in the aftermarkets for da Vinci service and the repair and replacement of EndoWrists.

Footnote 11: *Id.* at 10

Footnote 12: Intuitive (Form 10-K), at 9 (Feb. 6, 2017).

Footnote 13: Intuitive (Form 10-K), at 10 (Feb. 7, 2020) (3,531 robots in the U.S. as of December 31, 2019).

41. Intuitive admits that in its 10-K for the year ended December 31, 2020, Intuitive reported that it had an installed base of 3,720 da Vincis in the United States, but otherwise denies the allegations in the first sentence of paragraph 41. Intuitive admits that in its 10-K for the year ended December 31, 2016, Intuitive reported an installed base of 2,563 da Vincis, and that between December 31, 2016, to December 31, 2020, Intuitive’s installed base grew by 45%, but otherwise denies the allegations in the second sentence of paragraph 41. Intuitive admits that in its 10-K for the year ended December 31, 2019, Intuitive reported an installed base of 3,531 da

Vincis in the United States. Intuitive admits that its installed base grew more than 5% between December 31, 2019, and December 31, 2020, but otherwise denies the allegations in the third sentence of paragraph 41, except to the extent the third sentence of paragraph 41 further characterizes and quotes from Intuitive's 10-K for the fiscal year ended on December 31, 2019, Intuitive respectfully refers to that filing for its full context and contents. Intuitive denies the allegations in the fourth sentence of paragraph 41.

Paragraph 42: The da Vinci is a minimally invasive soft tissue surgical robot and may be used to perform a variety of surgical procedures including general, gynecologic, urologic, cardiothoracic, and head and neck surgeries. While other companies have introduced products in the field of robot-assisted surgery, most of those machines cannot be used for minimally invasive soft tissue surgeries and none is a significant competitor in the minimally invasive surgical robot market. For example, a natural orifice surgical robot allows a surgeon to insert a flexible scope with a camera into the abdominal cavity via one of the body's natural orifices. The surgeon may then perform throat, neck, or colorectal surgical procedures. However, the robot can only operate instruments introduced through the tube inserted into the natural orifice. It also is not indicated for pediatric use. The constraints imposed by both the mode of access and the limited availability of tools for use with natural orifice surgical robots pose several challenges for surgeons and preclude it from competing in the minimally invasive surgical robot market. Likewise, orthopedic robots, which are designed for assisting in the removal of bone and aligning prosthetics for knee and hip replacement, are not indicated for use in minimally invasive soft tissue surgery and are not a practical substitute for minimally invasive surgical robots.

42. Intuitive admits that da Vincis are designed to enable surgeons to perform a wide range of surgical procedures, within gynecologic, urologic, general surgery, cardiothoracic and head and neck specialties, but otherwise denies the allegations in the first sentence of paragraph 42. Intuitive denies the allegations in the second, seventh and eighth sentences of paragraph 42. Intuitive denies the allegations in the third, fourth, fifth and sixth sentences of paragraph 42 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 43: In 2020, approximately 876,000 procedures were performed using the da Vinci in the U.S.¹⁴

Footnote 14: Intuitive (Form 10-K), at 60 (Feb. 10, 2021).

43. Intuitive admits that in its 10-K for the year ended December 31, 2020, Intuitive

reported that approximately 876,000 procedures were performed using da Vincis in the United States. Intuitive otherwise denies the allegations in paragraph 43, except states that to the extent paragraph 43 further characterizes Intuitive's 10-K for the year ended December 31, 2020, Intuitive respectfully refers to that filing for its full context and contents.

Paragraph 44: The da Vinci ranges in price from \$500,000 to \$2.5 million. Intuitive reported \$830.7 million in revenue from da Vinci sales in the U.S. in 2019, accounting for 61.7% of robot sales worldwide.¹⁵

Footnote 15: Intuitive (Form 10-K), at 87 (Feb. 7, 2020).

44. Intuitive admits that the da Vinci generally sells for between \$500,000 and \$2.5 million, depending upon the model, configuration and geography. Intuitive admits that in its 10-K for the year ended December 31, 2019, Intuitive reported \$830.7 million in revenue from da Vinci sales in the United States, accounting for 61.7% of da Vinci sales worldwide. Intuitive otherwise denies the allegations in paragraph 44, except states that to the extent paragraph 44 further characterizes Intuitive's 10-K for the year ended December 31, 2019, Intuitive respectfully refers to that filing for its full context and contents.

Paragraph 45: There is a national geographic market for minimally invasive surgical robots in the U.S. The FDA regulates the approval of all medical equipment in the U.S., including minimally invasive surgical robots. Manufacturers who wish to sell minimally invasive surgical robots in the U.S. must obtain FDA approval before doing so.

45. Intuitive denies the allegations in the first sentence of paragraph 45. Intuitive admits that the Food and Drug Administration ("FDA") regulates the clearance of minimally invasive surgical robotic systems in the United States and that manufacturers of minimally invasive surgical robotic systems must obtain FDA clearance before selling the systems in the United States, but otherwise denies the allegations in the second and third sentences of paragraph 45 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 46: U.S. hospitals cannot lawfully operate non-FDA-approved minimally invasive

surgical robots. Thus, minimally invasive surgical robots approved only for use abroad are not substitutes for FDA-approved minimally invasive surgical robots, even though Intuitive has set its da Vinci prices above competitive levels.

46. Intuitive admits that FDA clearance is required for minimally invasive surgical robotic systems to be lawfully used by hospitals in the United States, but otherwise denies the allegations in paragraph 46.

Paragraph 47: From 1999 to 2017, the da Vinci robot was the only minimally invasive surgical robot cleared by the FDA for sale in the domestic market. Intuitive installed more than 2,000 da Vinci robots during its time as the only manufacturer in the minimally invasive surgical robot market. From 2017 through today, Intuitive has maintained at least a 98% market share in the worldwide and domestic minimally invasive surgical robot markets.

47. Intuitive admits that the da Vinci was cleared by the FDA for general laparoscopic surgery in 2000, but otherwise denies the allegations in the first sentence of paragraph 47. Intuitive admits that as of December 31, 2017, it had an installed base of 4,409 da Vincis worldwide, but otherwise denies the allegations in the second sentence of paragraph 47. Intuitive denies the allegations in the third sentence of paragraph 47.

Paragraph 48: The number of procedures performed using the da Vinci has typically increased at least 14% year-over-year since 2017, with a 1% decrease in procedures performed in 2020 due to the ongoing Coronavirus pandemic.¹⁶

Footnote 16: Intuitive (Form 10-K), at 60 (Feb. 10, 2021).

48. Intuitive denies the allegations in paragraph 48, except states that to the extent paragraph 48 further characterizes and quotes Intuitive's 10-K for the year ended December 31, 2020, Intuitive respectfully refers to that filing for its full context and contents.

Paragraph 49: A company called Asensus (formerly known as TransEnterix) received FDA approval for commercial sale of its surgical robot, shown below in Figure 2, in the U.S. in 2017.¹⁷ Sold under the Senhance brand name, the robot is approved to perform gynecological, colorectal, and cholecystectomy surgeries, and inguinal hernia repair. It cannot perform certain surgeries, such as cardiothoracic or urological surgeries, making it less functional than the da Vinci. Nor is it approved for pediatric use. Asensus reported just \$90,000 in revenues from sales related to its Senhance surgical robot in 2019 in the U.S. and has had "limited commercial success to date" in the U.S.¹⁸

Footnote 17: Asensus (f.k.a. TransEnterix) (Form 10-K), at 4 (March 16, 2020).

Footnote 18: *Id.* at 13.

Footnote 19: *TransEnterix, Inc. Unveils New Brand Identity for Robotic Surgical System: Establishes Senhance™ to Communicate New Era in Robotic Surgery*, BusinessWire (Sept. 7, 2016), <https://www.businesswire.com/news/home/20160907005187/en/TransEnterix-Inc.-Unveils-New-Brand-Identity-for-Robotic-Surgical-System>.

Figure 2: Senhance Surgical Robot¹⁹
[IMAGE]

49. Intuitive denies the allegations in paragraph 49 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein, except states that to the extent paragraph 49 characterizes and quotes from Asensus's 10-K dated March 16, 2020, Intuitive respectfully refers to that filing for its full context and contents.

Paragraph 50: Neither Asensus nor any other company is a significant competitor in the minimally invasive surgical robot market.

50. Intuitive denies the allegations in paragraph 50.

Paragraph 51: While other companies have introduced products in the field of robotic-assisted surgery, these machines are not part of the minimally invasive surgical robot market and thus are not competitors of Intuitive's da Vinci. For example, a company called Medrobotics received clearance for a natural orifice surgical robot on July 23, 2015. However, the robot, sold under the Flex system brand name, can only operate instruments introduced through the tube inserted into the natural body orifice. Thus, due to its design limitations, it is indicated for only a limited range of procedures and is not a direct competitor to the da Vinci. The Flex system has a de minimis presence in the marketplace.

51. Intuitive denies the allegations in the first, fourth and fifth sentences of paragraph 51. Intuitive denies the allegations in the second and third sentences of paragraph 51 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 52: Medtronic and Stryker make devices for use in orthopedic surgeries. Medtronic makes the Mazor X Stealth device for use specifically in spinal implant surgery, and Stryker makes the Mako products for use in aligning implants in knee and hip replacement surgeries. These orthopedic surgery robots are not substitutes for, and do not compete with, Intuitive's da Vinci robots, which are not used for orthopedic surgeries. The orthopedic surgery robots are not part of the minimally invasive surgical robot market.

52. Intuitive denies the allegations in the first and second sentences of paragraph 52

because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the third and fourth sentences of paragraph 52.

Paragraph 53: Prior to FDA approval of the Senhance for minimally invasive robotic surgeries, Intuitive maintained a 100% market share for minimally invasive surgical robots. Even after Senhance and Medrobotics entered the robotic surgery market, Intuitive still maintains at least a 98% market share in the market for minimally invasive surgical robots because neither company has been able to gain sufficient U.S. market share to pose a meaningful threat to Intuitive's dominance. While Intuitive shipped 728 da Vincis throughout the U.S. in 2019, Asensus did not ship any Senhances domestically and Medrobotics shipped fewer than 10 Flex robots worldwide.

53. Intuitive denies the allegations in the first and second sentences of paragraph 53. Intuitive admits that in its 10-K for the year ended December 31, 2019, Intuitive reported that 728 da Vincis were shipped into the United States, but otherwise denies the allegations in the third sentence of paragraph 53 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 54: External literature characterizes Intuitive as possessing monopoly power in the minimally invasive surgical robot market. For example, one 2017 study in the Journal of Minimal Access Surgery noted that Intuitive's da Vinci was "the only commercially available robotic equipment" at the time.²⁰ Similarly, a 2019 study on robotic surgery noted that Intuitive "[e]ffectively [possessed] a monopoly" in the robotic surgery industry.²¹

Footnote 20: Gkegkes, I. D., Mamais, I. A., & lavazzo, C. (2017). Robotics in General Surgery: A Systematic Cost Assessment. Journal of Minimal Access Surgery, 13(4), 243-255. <https://doi.org/10.4103/0972-9941.195565>

Footnote 21: Perez, R. E. & Schwaitzberg, S. D., Robotic Surgery: Finding Value in 2019 and Beyond, Ann. Laparosc. Endosc. Surg. 2019; 4:51.

54. Intuitive denies the allegations in paragraph 54, except states that to the extent paragraph 54 purports to characterize and quote from a 2017 Journal of Minimal Access Surgery article and a 2019 Annals of Laparoscopic and Endoscopic Surgery article, Intuitive respectfully refers to those articles for their full context and contents.

Paragraph 55: Switching minimally invasive surgical robots is not feasible. First, minimally invasive surgical robots require significant capital investment not only in the robot itself but also in the necessary surgical instruments and required service contracts. Further, operating a minimally invasive surgical robot requires many hours of training. Switching minimally invasive

surgical robots would not only be costly—as minimally invasive surgical robots have an average sales price of \$1.5 million and many of Intuitive’s U.S. customers have at least two such robots, representing significant capital investment—but also would require substantial time to retrain surgeons and supporting staff to operate the new robot, during which time a hospital may not be able to offer minimally invasive robotic surgical services. Surgeons at a hospital attempting such a transition would need to abandon the da Vinci surgical methods they have been performing for years (for some, their entire careers) and learn how to perform surgeries with different minimally invasive surgical robots. This process would be both costly and likely to generate substantial resistance, particularly given that Intuitive invests heavily to ensure that doctors and medical students are trained to use, and be dependent on, the da Vinci. Intuitive has aggressively marketed da Vincis and has paid surgeons substantial sums—in some cases, millions of dollars to promote da Vincis by, e.g., giving talks about them, teaching others how to use them, and testing and writing reviews of them. Some surgeons would switch hospitals rather than switch minimally invasive surgical robots, further driving up costs for any hospital that sought to replace the da Vinci with competing robots. Finally, according to Restore, Intuitive extracts from its da Vinci customers the contractual commitment not to purchase competing robots.²²

Footnote 22: Restore Second Amended Complaint (March 29, 2021) (ECF No. 77) (“Restore Second Amended Complaint”) ¶ 23, *Restore Robotics, LLC v. Intuitive Surgical, Inc.*, Case No. 5:19-cv-55-TKW-MJF (N.D. Fl.).

55. Intuitive denies the allegations in the first, second, third, fourth, fifth, sixth and eighth sentences of paragraph 55 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the seventh sentence of paragraph 55. Intuitive denies the allegations in ninth sentence of paragraph 55, except states that to the extent paragraph 55 purports to characterize and quote from Restore’s Second Amended Complaint, Intuitive respectfully refers to Intuitive’s Answer to Restore’s Second Amended Complaint (ECF No. 81) for Intuitive’s responses to the cited allegations.

Paragraph 56: There are high barriers to entry into the minimally invasive surgical robot market. The cost to develop a minimally invasive surgical robot is substantial, especially because Intuitive maintains an extensive portfolio of patents that block the development of competing minimally invasive surgical robots. Indeed, Intuitive has stated in a court pleading that as of December 31, 2018, it held ownership or exclusive field-of-use licenses for more than 3,000 U.S. and foreign patents.²³ Intuitive is notorious for aggressively amassing and enforcing these patents. Furthermore, clearance by regulatory agencies, such as the FDA, is an extensive and uncertain process.

Footnote 23: Intuitive’s Answer and Affirmative Defense (Sept. 30, 2019) (ECF No. 32) ¶ 23, *Restore Robotics, LLC v. Intuitive Surgical, Inc.*, Case No. 5:19-cv-55-TKW-MJF (N.D. Fl.).

56. Intuitive denies the allegations in the first sentence of paragraph 56. Intuitive admits that as of December 31, 2020, it held ownership or exclusive field-of-use licenses for more than 4,000 United States and foreign patents and that there is a cost to developing a minimally invasive surgical robotic system, but otherwise denies the allegations in the second sentence of paragraph 56. Intuitive admits the allegations in the third sentence of paragraph 56. Intuitive denies the allegations in the fourth and fifth sentences of paragraph 56 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 57: The medical equipment repair and maintenance services industry is a \$3.3 billion market in the U.S. and is expected to grow by 1.5% per year between 2020 and 2025.²⁴

Footnote 24: Jack Curran, “Medical Equipment Repair & Maintenance Services,” IBIS World, June 2020, at 7.

57. Intuitive denies the allegations in paragraph 57, except states that to the extent paragraph 57 purports to characterize and quote from a February 2020 IBIS World article, Intuitive respectfully refers to that article for its full context and contents.

Paragraph 58: There is a relevant aftermarket in the U.S. for the service of da Vincis. After the da Vinci is installed, it requires regular maintenance and service. The primary aspects of the da Vinci service aftermarket are the routine maintenance of the da Vinci and the repair of the da Vinci when necessary.

58. Intuitive denies the allegations in the first and third sentences of paragraph 58. Intuitive admits the allegations in the second sentence of paragraph 58.

Paragraph 59: Recognizing this need for regular repair and maintenance, Intuitive conditions the purchase or lease of a da Vinci on the customer entering into a da Vinci service contract.²⁵ The initial service contract is typically five years, with the first year of service being free and the remaining four years ranging in price from \$80,000 to \$190,000 per year.²⁶ At present, Intuitive requires its customers to purchase one of two types of service plans for its da Vincis, either:

- i. the Complete Care Service Plan, which includes advance exchange program, remote software update, sterile reprocessing support, technical support, onsite access and monitoring, and da Vinci surgery customer portal; or
- ii. the Premium Care Service Plan, which includes everything in the Complete Care service plan and provides extended service hours, faster response time, expedited replacement parts, and a 5% discount on technology upgrades, among other things.²⁷

Footnote 25: Intuitive (Form 10-Q), at 29 (June 2020).

Footnote 26: Intuitive (Form 10-K), at 55 (Feb. 10, 2021).

Footnote 27: Da Vinci service plan brochures are available at <https://www.intuitive.com/en-us/products-and-services/da-vinci/services##>.

59. Intuitive admits that the SLSA prohibits customers from engaging any unauthorized third party to service its da Vincis, but otherwise denies the allegations in the first sentence of paragraph 59. Intuitive admits that in its 10-K for the fiscal year ending December 31, 2020, Intuitive stated that it “typically enter[s] into service contracts at the time systems are sold or leased at an annual fee between \$80,000 and \$190,000, depending upon the configuration of the underlying system and composition of the services offered under the contract. These service contracts have generally been renewed at the end of the initial contractual service period,” but otherwise denies the allegations in the second sentence of paragraph 59. Intuitive admits that it offers service plans including the Complete Care Service Plan and the Premium Care Service Plans, but otherwise denies the allegations in the third sentence of paragraph 59, except states that to the extent paragraph 59 purports to characterize and quote from Intuitive’s website, Intuitive respectfully refers to its website for its full context and contents.

Paragraph 60: At the end of each contract term, Intuitive offers an additional service contract. Intuitive uses its exclusive access to certain replacement robot parts, as described below, see *infra* at paragraphs 65-66, to pressure its customers to renew their service contracts.

60. Intuitive denies the allegations in paragraph 60.

Paragraph 61: The terms of the service contracts exempt Intuitive from its obligation to perform any service or repair if the customer or a third party (such as an IRC) services the da Vinci, even if Intuitive’s service contract did not cover the service.

61. Intuitive denies the allegations in paragraph 61.

Paragraph 62: Customers have little or no information for projecting the costs of surgical robot parts or service, even with flat-rate service agreements. In order to forecast the cost per use, the customer must know how often the robot will be used. However, customers typically cannot forecast demand for a surgical robot: surgeons may have varying degrees of adaptation to a surgical robot at a new location or for a new procedure; competing hospitals may or may not acquire their own robots; and the FDA may or may not add new indications for use of the robots.

These and other unknown factors will impact how often a da Vinci is used, and thus bear on part replacement and service costs.

62. Intuitive denies the allegations in paragraph 62 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 63: There are high barriers to entry in the da Vinci service aftermarket. First, the terms of the da Vinci Sales Agreements and the tied da Vinci service contracts prohibit customers from servicing their da Vinci either themselves or through an IRC. Lessees of the da Vinci must enter the same service contract for the term of the lease. This discourages customers from seeking da Vinci repair or maintenance services from IRCs.

63. Intuitive denies the allegations in the first, second and third sentences of paragraph 63. Intuitive denies the allegations in the fourth sentence of paragraph 63 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 64: Intuitive encrypts and hides from robot owners and IRCs the service software necessary to: (a) test the robot arms during preventative maintenance; (b) input Intuitive serial numbers after replacing da Vinci robot parts; and (c) remove the reminder message after performing preventative maintenance or repairing the robot.

64. Intuitive admits that its proprietary service software is necessary to perform preventative maintenance and to repair the da Vinci, but otherwise denies the allegations in paragraph 64.

Paragraph 65: Intuitive is also the only manufacturer of da Vinci robot parts. For calendar year 2020, Intuitive had an overall gross margin on product sales of more than 66%, a slight dip from the pre-pandemic gross margin of more than 70% on product sales that Intuitive enjoyed in calendar year 2019. Upon information and belief, Intuitive realizes gross margins in excess of 90% for da Vinci parts.

65. Intuitive denies the allegations in the first and third sentences of paragraph 65. Intuitive admits that in its 10-K for the year ended December 31, 2020, Intuitive reported its product gross profit represented 66.2% of product revenue. Intuitive admits that in its 10-K for the year ended December 31, 2019, its product gross profit represented 70.2% of product revenue, but otherwise denies the allegation in the second sentence of paragraph 65.

Paragraph 66: Da Vinci parts are not available from other sources. This is due in part to patent protection and development costs, but also to the fact that, in at least some instances, the da Vinci requires an Intuitive product serial number for the replacement part in order to restart the robot. Intuitive also excludes competition in the sale of da Vinci parts by requiring customers to purchase a parts and service plan from Intuitive with the purchase or lease of the da Vinci. Intuitive requires customers to purchase da Vinci service from Intuitive to get access to da Vinci parts, and sells da Vinci parts only directly to da Vinci customers and only as part of the robot service.

66. Intuitive denies the allegations in paragraph 66.

Paragraph 67: Quality control is not a valid business justification for excluding third parties from servicing and repairing da Vincis. Indeed, Intuitive contracts with third party distributors of da Vincis outside the U.S. to service da Vincis.

67. Intuitive denies the allegations in the first sentence of paragraph 67. Intuitive admits that it contracts with distributors in other countries to service da Vincis, but otherwise denies the allegations in the second sentence of paragraph 67.

Paragraph 68: While servicing the da Vinci requires specialized training and knowledge, there are IRCs that have the skill and capacity to service da Vincis. For example, Restore, a surgical robotic repair company based in Florida, specializes in the da Vinci and hires da Vinci—certified field service engineers with prior training and experience working at Intuitive to provide da Vinci service. Restore began offering service contracts for the da Vinci in 2018 and typically offers service at rates of less than 50% of the effective rates offered by Intuitive. Restore states that it can service da Vincis worldwide. Great Lakes Robotics (“Great Lakes”) is another IRC that claims to be an “authorized” provider of da Vinci services through its partnership with Restore.²⁸ Other biomedical service and repair companies likely would enter the market to service da Vincis in the absence of Intuitive’s anticompetitive conduct.

Footnote 28: <https://www.greatlakesrobotics.net/>

68. Intuitive admits that servicing da Vincis requires specialized training and knowledge, but otherwise denies the allegations in the first sentence of paragraph 68. Intuitive admits that Restore has hired former Intuitive personnel in the past, but otherwise denies the allegations in the second sentence of paragraph 68. Intuitive denies the allegations in the third, fourth, fifth and sixth sentences of paragraph 68 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein, except states that to the extent paragraph 68 purports to characterize and quote from the Great Lakes Robotics website, Intuitive

respectfully refers to that webpage for its full context and contents.

Paragraph 69: Intuitive installs and services da Vincis throughout the U.S., and U.S.-based IRCs such as Restore have the expertise to service da Vincis throughout the U.S.

69. Intuitive admits that it installs and services da Vincis throughout the United States, but otherwise denies the allegations in paragraph 69.

Paragraph 70: Intuitive sells and services da Vincis through third party distributors in unspecified countries outside the U.S. and provides them with a toolkit with all the documentation, software, and passwords necessary to service the da Vinci. Distributors may use their toolkits to service da Vincis only in their territory. No one else has access to the toolkit, not even customers.

70. Intuitive admits that it contracts with certain distributors to sell and service da Vincis in certain countries outside the United States, and as part of the contractual relationship, provides certain tools and test equipment to the distributors but not to other third parties, including customers. Intuitive otherwise denies the allegations in paragraph 70.

Paragraph 71: U.S. hospitals are thus unable to hire service providers from other countries, despite Intuitive raising its da Vinci service prices above competitive levels.

71. Intuitive denies the allegations in paragraph 71 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 72: Intuitive exploits its monopoly power in the primary market for minimally invasive surgical robots to acquire and maintain monopoly power in the aftermarket for da Vinci service. Thus, it can and does exclude competition and maintain supracompetitive prices for da Vinci service.

72. Intuitive denies the allegations in paragraph 72.

Paragraph 73: First, as described above, Intuitive uses contractual ties to lock its da Vinci customers into servicing agreements with Intuitive, rather than any IRCs. The terms of the Sales Agreements and service agreements forbid purchasers from using third party repair or maintenance services of any kind. Intuitive even reserves the right to void the entire service contract of any customer that seeks any kind of service, maintenance, or repair for its da Vinci through an IRC. This effectively forecloses competition in the da Vinci service aftermarket.

73. Intuitive denies the allegations in the first and fourth sentences of paragraph 73. Intuitive admits that its SLSAs prohibit customers from engaging any unauthorized third party to

service its da Vincis and from engaging any unauthorized third party to repair, refurbish, or recondition EndoWrists at any time. Intuitive admits that its SLSAs include a right for Intuitive to void the service contract of any customer that uses unauthorized third-party service, repair or maintenance for its da Vinci. Intuitive otherwise denies the allegations in the second and third sentences of paragraph 73.

Paragraph 74: Second, as also described above, Intuitive designed the da Vinci to minimize the ability of a third-party to perform maintenance on or manufacture replacement parts for the robot.

74. Intuitive denies the allegations in paragraph 74.

Paragraph 75: Third, as described below, Intuitive aggressively enforces these contractual and technological ties in order to prevent any IRC from developing substantial market share or reaching efficient scale in the aftermarket for da Vinci service.

75. Intuitive denies the allegations in paragraph 75.

Paragraph 76: All these measures deter customers from attempting to service their da Vincis through an IRC, further solidifying Intuitive's monopoly in the da Vinci service aftermarket.

76. Intuitive denies the allegations in paragraph 76.

Paragraph 77: For example, when Intuitive learned that a hospital system was using Restore for robot service, Intuitive informed the customer that its hospitals would not be able to purchase da Vinci parts for use in any service performed by Restore. On or about February 12, 2019, Intuitive also sent a letter to Restore demanding that Restore "immediately cease and desist" from "contacting Intuitive's customers to offer services related to Intuitive's products."

77. Intuitive denies the allegations in the first sentence of paragraph 77. Intuitive admits that on or about February 12, 2019, it sent a letter to Restore Robotics LLC demanding that Restore Robotics LLC cease and desist from, among other things, "marketing and offering a servicing process in the course of which the use counter of Endo Wrist® instruments' memory device is manipulated and/or replaced to permit more than ten uses" or "contacting Intuitive's customers to offer services related to Intuitive's products," but otherwise denies the allegations in the second sentence of paragraph 77.

Intuitive 78: Intuitive’s exclusionary conduct in the aftermarket for da Vinci service is further illustrated by its response when Ardent Health Service (“Ardent”) used Restore to service da Vincis. Ardent, owner of Hillcrest Medical Center and Hillcrest Hospital South (“Hillcrest”) in Tulsa, Oklahoma, allowed its da Vinci service contracts with Intuitive to expire for its two robots at Hillcrest Medical Center and its one robot at Hillcrest Hospital South. Ardent had not been having any problems with the robots. Intuitive was aware that Hillcrest was considering Restore for its da Vinci service.²⁹

Footnote 29: Restore Second Amended Complaint ¶ 64.

78. Intuitive denies the allegations in the first sentence of paragraph 78. Intuitive admits that Ardent Health Service allowed service agreements with Intuitive for its da Vincis to expire, but otherwise denies the allegations in the second sentence of paragraph 78. Intuitive denies the allegations in the third sentence of paragraph 78 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive admits that by February 2020, individuals at Intuitive believed that Hillcrest was using or considering using Restore Robotics for its da Vinci service, but otherwise denies the allegations in the fourth sentence of paragraph 78.

Paragraph 79: On December 27, 2019, Intuitive removed Hillcrest from the customer portal and placed the three robots on time-and-materials status for any robot service, which includes a travel and labor rate of \$995 per hour. On that same day, Hillcrest Medical Center noticed a blank vision cart touchscreen on one of its robots. Intuitive informed Hillcrest that the monitor needed to be replaced and quoted time and materials of more than \$25,000. Hillcrest hired Restore to troubleshoot the issue. On January 11, 2020, Restore installed a new power supply for the touchscreen monitor and confirmed that the robot was fully functioning. The price was \$7,100.³⁰
Footnote 30: *Id.* at 65.

79. Intuitive admits that upon Hillcrest’s request, Intuitive agreed to place three Hillcrest systems on a time and materials status for da Vinci service, which has a labor and travel rate of \$995 per hour, and quoted a preliminary time and materials rate of over \$25,000 to replace the touch screen on the vision cart, but otherwise denies the allegations in the first and third sentences of paragraph 79. Intuitive denies the allegations in the second, fourth, fifth and sixth sentences of paragraph 79 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. To the extent paragraph 79 purports to

characterize Restore's Second Amended Complaint, Intuitive respectfully refers to Intuitive's Answer to Restore's Second Amended Complaint (ECF No. 81) for Intuitive's responses to the cited allegations.

Paragraph 80: On January 14, 2020, Hillcrest reported an issue with a robot arm on the da Vinci at Hillcrest Hospital South. Intuitive informed Hillcrest that it would cost more than \$100,000 to replace the arm plus an additional sum for preventative maintenance for the da Vinci to be operational. Hillcrest contacted Restore to troubleshoot the issue. Restore informed Hillcrest that Restore could replace the arm if necessary but did not have the toolkit to access the robot software and input the serial number for the replacement arm. Intuitive would have to input the serial number for any replacement arm for the da Vinci to be operational.³¹

Footnote 31: *Id.* at 66.

80. Intuitive admits that Hillcrest had an issue with a robot arm on a da Vinci system that Hillcrest needed Intuitive to fix, but otherwise denies the allegations in paragraph 80. To the extent paragraph 80 purports to characterize Restore's Second Amended Complaint, Intuitive respectfully refers to Intuitive's Answer to Restore's Second Amended Complaint (ECF No. 81) for Intuitive's responses to the cited allegations.

Paragraph 81: On January 16, 2020, Restore was able to repair, rather than replace, the robot arm for \$3,975. The da Vinci was operational but had two remaining error codes. Restore could not troubleshoot the remaining errors without access to the software on the da Vinci and informed Hillcrest that it would need to contact Intuitive regarding the remaining error codes.³²

Footnote 32: *Id.* at 67.

81. Intuitive denies the allegations in paragraph 81.

Paragraph 82: On January 17, 2020, Kara Andersen Reiter, Intuitive SVP and General Counsel, and Romain St. Denis, Intuitive VP, notified the CEO, the VP of Risk Management, and the Chief Medical Officer of Ardent Health Services in writing that Intuitive had learned that Ardent was "having or intends to have" its da Vincis serviced by an "unauthorized third party."³³

Footnote 33: *Id.* at 68.

82. Intuitive admits that on January 17, 2020, Kara Andersen Reiter and Romain Denis notified Ardent Health Services that Intuitive "understand[s] that Ardent Health Services is using or considering using 'refurbished' EndoWrist® instruments, obtained from and/or modified by a third party for use beyond the programmed number of uses" and that "[b]ased on

the terms of the Agreement and the patient safety implications of the Systems being used with instruments refurbished by an unauthorized third party, Intuitive may no longer accept your service calls for such Systems.” Intuitive otherwise denies the allegations in paragraph 82, except states that to the extent paragraph 82 purports to characterize Restore’s Second Amended Complaint, Intuitive respectfully refers to Intuitive’s Answer to Restore’s Second Amended Complaint (ECF No. 81) for Intuitive’s responses to the cited allegations.

Paragraph 83: In the letter, Intuitive explained that third parties did not have the “software tools necessary for proper System maintenance.” Intuitive further stated that “Intuitive may no longer accept your service calls for Systems that were previously serviced by an unauthorized third party. Should Intuitive or its personnel determine, after having accepted a service call or a purchase order for a service call, such as after an Intuitive Field Service Engineer arrives at your site for a service call, that the System has been previously serviced by an unauthorized third party, Intuitive may not provide service for such a System.”³⁴

Footnote 34: *Id.* at 69.

83. Intuitive admits that it stated, “[A] hospital robotics coordinator learned that the third party personnel did not have the software tools necessary for proper System maintenance,” but otherwise denies the allegations in the first sentence of paragraph 83. Intuitive admits the allegations in the second and third sentences of paragraph 83. To the extent paragraph 83 purports to characterize Restore’s Second Amended Complaint, Intuitive respectfully refers to Intuitive’s Answer to Restore’s Second Amended Complaint (ECF No. 81) for Intuitive’s responses to the cited allegations.

Paragraph 84: On January 30, 2019, Chris Goss, the Intuitive field service engineer responsible for Hillcrest, contacted the surgery manager at Hillcrest Medical Center in Tulsa, Oklahoma. Mr. Goss explained he could monitor the da Vinci remotely and threatened to shut down the da Vincis at Hillcrest if the hospital signed a service contract with Restore. Mr. Goss said Intuitive would make Hillcrest’s da Vincis “a big paper weight” if Hillcrest chose to use a third party for its robot service.³⁵

Footnote 35: *Id.* at 70.

84. Intuitive admits that Chris Goss contacted the surgery manager at Hillcrest Medical Center, but otherwise denies the allegations in paragraph 84. To the extent paragraph

84 purports to characterize Restore's Second Amended Complaint, Intuitive respectfully refers to Intuitive's Answer to Restore's Second Amended Complaint (ECF No. 81) for Intuitive's responses to the cited allegations.

Paragraph 85: Shortly thereafter, the da Vinci ceased to function in the middle of a procedure. The surgeon had to convert the procedure to open surgery with the patient on the operating table. Afterwards, Hillcrest disconnected the data cable that provides the remote connection between the da Vinci and Intuitive.³⁶

Footnote 36: *Id.* at 71.

85. Intuitive admits Hillcrest had a da Vinci that failed and required repair, but otherwise denies the allegations in the first and second sentences of paragraph 85 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the third sentence of paragraph 85. To the extent paragraph 85 purports to characterize Restore's Second Amended Complaint, Intuitive respectfully refers to Intuitive's Answer to Restore's Second Amended Complaint (ECF No. 81) for Intuitive's responses to the cited allegations.

Paragraph 86: On May 6, 2020, Hillcrest contacted Restore to troubleshoot a robot arm on the da Vinci in one of its operating rooms at Hillcrest Medical Center. Restore reminded Hillcrest that Intuitive would have to perform any repair of the robot arm because the repair or replacement of the arm would require access to the da Vinci software through the service laptop and the service keys and that Intuitive does not provide such access to the owner or IRCs.³⁷

Footnote 37: *Id.* at 72.

86. Intuitive denies the allegations in paragraph 86 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. To the extent paragraph 86 purports to characterize Restore's Second Amended Complaint, Intuitive respectfully refers to Intuitive's Answer to Restore's Second Amended Complaint (ECF No. 81) for Intuitive's responses to the cited allegations.

Paragraph 87: On May 7, 2020, Hillcrest contacted Intuitive for repair of the robot arm on a time-and-materials basis. Intuitive quoted an initial price to troubleshoot the arm. Ardent approved the quote. Later that day, Intuitive revised its quote to include an additional sum for preventative maintenance. Early on May 8, 2020, Ardent approved the work order.³⁸

Footnote 38: Id. at 73.

87. Intuitive admits that on May 7, 2020, Hillcrest contacted Intuitive for repair, Intuitive quoted an initial price to troubleshoot an arm on a da Vinci, subsequently revised the quote and Ardent approved the work order. Intuitive otherwise denies the allegations in paragraph 87, except states that to the extent paragraph 87 purports to characterize Restore's Second Amended Complaint, Intuitive respectfully refers to Intuitive's Answer to Restore's Second Amended Complaint (ECF No. 81) for Intuitive's responses to the cited allegations.

Paragraph 88: Later that day, Intuitive instructed its field service engineer to cease the repair of the robot arm because the engineer observed that other parts elsewhere on the da Vinci had not been installed by Intuitive. On May 11, 2020, Intuitive demanded that Ardent agree to the removal of any parts that had been replaced or repaired by anyone other than Intuitive and pay the additional sum to Intuitive for "preventative maintenance" on the da Vinci, in addition to the cost of the repair of the robot arm, before Intuitive would restore functionality to the da Vinci. In fact, the sole "part" that Restore had replaced was the battery, which Restore had replaced with the exact same model from the exact same battery manufacturer.³⁹

Footnote 39: Id. at 74.

88. Intuitive denies the allegations in paragraph 88, except states that to the extent paragraph 88 purports to characterize Restore's Second Amended Complaint, Intuitive respectfully refers to Intuitive's Answer to Restore's Second Amended Complaint (ECF No. 81) for Intuitive's responses to the cited allegations.

Paragraph 89: On May 12, 2020, Ardent agreed to the demands and beseeched Intuitive to "fix the robot ASAP." Shortly thereafter, Ardent signed a one-year service contract with Intuitive for the da Vinci in question at Hillcrest retroactive to the prior contract expiration date of December 27, 2019 at a price of more than \$100,000.⁴⁰

Footnote 40: Id. at 75.

89. Intuitive admits Hillcrest signed a one-year service contract with Intuitive retroactive to December 27, 2019, at a price of more than \$100,000, but otherwise denies the allegations in paragraph 89. To the extent paragraph 89 purports to characterize Restore's Second Amended Complaint, Intuitive respectfully refers to Intuitive's Answer to Restore's Second Amended Complaint (ECF No. 81) for Intuitive's responses to the cited allegations.

Paragraph 90: As a direct result of this type of exclusionary conduct, Intuitive has maintained a market share in the da Vinci service aftermarket of more than 99% for nearly 20 years. In 2019, Intuitive reported \$508.4 million in revenues for service to its customers in the U.S.

90. Intuitive denies the allegations in the first sentence of paragraph 90. Intuitive admits that in its 10-K for the year ended December 31, 2019, Intuitive reported \$508.4 million in revenues for services to its customers in the United States.

Paragraph 91: There is a relevant aftermarket for the repair and replacement of EndoWrists that is separate from the minimally invasive surgical robot market and the da Vinci service aftermarket (the “EndoWrist Repair and Replacement Aftermarket”). EndoWrists are the only FDA-approved surgical instruments that are compatible with the da Vinci. Therefore, hospitals must have EndoWrists in order to use the da Vinci.

91. Intuitive denies the allegations in the first sentence of paragraph 91. Intuitive admits that EndoWrists used with da Vincis have received FDA clearance, but otherwise denies the allegations in the second and third sentences of paragraph 91.

Paragraph 92: Intuitive exercises complete control over the design, manufacture, sale, and replacement of EndoWrists. Although Intuitive maintains a significant patent portfolio in its surgical robots, any blocking patents for its EndoWrist instruments are long expired. Intuitive maintains a “Patent Notice” web page for its products. Virtually all the patents covering core structure and operations for the “EndoWrist” and “Accessories” are expired.

92. Intuitive admits that it designs, manufactures and sells replacement EndoWrists, but otherwise denies the allegations in the first sentence of paragraph 92. Intuitive admits that it has numerous patents related to its da Vincis and EndoWrists, but otherwise denies the allegations in the second and fourth sentences of paragraph 92 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive admits that it has a “Patent Notice” web page, but otherwise denies the allegations in the third sentence of paragraph 92.

Paragraph 93: Intuitive sells over 80 different types of surgical instruments for use with the da Vinci. As shown in Figure 3, below, EndoWrists are modeled after the human wrist and offer a greater range of motion than the human hand. Figure 4, below, depicts some of the EndoWrists available to hospitals.

Figure 3: EndoWrist modeled after human hand ⁽⁴¹⁾

[IMAGE]

Footnote 41: Palep J. H. (2009). Robotic assisted minimally invasive surgery. Journal of minimal access surgery, 5(1), 1-7. <https://doi.org/10.4103/0972-9941.51313>; Intuitive; and Longmore, S. K., Naik, G., & Gargiulo, G. D. (2020). Laparoscopic Robotic Surgery: Current Perspective and Future Directions. Robotics, 9(2), 42.

Figure 4: Some of the EndoWrists available for use with the da Vinci
[IMAGES]

93. Intuitive admits that it sells more than 80 different EndoWrists used with da Vincis that have received FDA clearance, but otherwise denies the allegations in the first sentence of paragraph 93. Intuitive admits that EndoWrists are modeled after the human hand and can achieve a greater range of motion than a human hand, but otherwise denies the allegations in the second sentence of paragraph 93 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein, except states that to the extent paragraph 93 purports to characterize a Journal of Minimal Access Surgery article, Intuitive respectfully refers to that article for its full context and contents. Intuitive admits the allegations in the third sentence of paragraph 93.

Paragraph 94: Intuitive sells a variety of EndoWrists with different tips for various surgical actions, including forceps, scissors, scalpels, and clamps. The movement at the instrument tip is controlled by tungsten cables located within the EndoWrist. (Tungsten cables are common in surgical robots, and surgical cables are among the parts that IRCs commonly repair). These tungsten cables are actuated by internal pulleys of the EndoWrist that mechanically interface with motors within the robot arms of the da Vinci. The motors within the robot arms in turn cause the movement of the instrument tip commanded by the surgeon by pulling or reining the tungsten cables. For the vast majority of EndoWrists, these mechanical components provide for all controls of the EndoWrist's instrument tip.

94. Intuitive sells compatible instruments and accessories customized for various surgical procedures, such as forceps, scissors, scalpels and clamps, but otherwise denies the allegations in the first sentence of paragraph 94. Intuitive denies the allegations in the second, fourth, fifth and sixth sentences of paragraph 94. Intuitive denies the allegations in the third sentence of paragraph 94 (which is bracketed) because it is without knowledge or information

sufficient to form a belief as to the truth of the allegations therein.

Paragraph 95: The da Vinci was designed to work exclusively with instruments manufactured and sold by Intuitive. Thus, EndoWrists are the only instruments compatible with the da Vinci.

95. Intuitive admits that it designed EndoWrists to work with its da Vincis, but otherwise denies the allegations in the first and second sentences of paragraph 95.

Paragraph 96: Intuitive installs a programmable memory chip inside each EndoWrist that limits the number of times the instrument may be used. The chip does not control the movement of the EndoWrist instrument tip, but instead stores certain information about the particular EndoWrist, including a model number specific to the type of EndoWrist, a part ID specific to the particular EndoWrist, a chip ID for the chip itself, and a counter value for the particular EndoWrist.

96. Intuitive admits it includes a programmed memory chip in each EndoWrist and that it has conducted rigorous testing and identified a maximum use limit for EndoWrists and that the maximum use limit ensures that instruments perform safely and reliably, but otherwise denies the allegations in the first sentence of paragraph 96. Intuitive admits that the allegations in the second sentence of paragraph 96 describe part of the functionality of the memory chip at issue.

Paragraph 97: The counter counts the number of times the EndoWrist is attached to a da Vinci robot arm, not an actual measure of use such as usage time, number of movements, or actuation time. The chip also does not monitor the components of the EndoWrist for conditions that could be indicative of actual or impending failure, such as the lack of response of the instrument tip to requested movement or a motor requiring excessive force to cause a desired movement of the tungsten cables.

97. Intuitive admits that it includes a programmed memory chip in each EndoWrist that, among other functions, counts the number of uses, but otherwise denies the allegations in the first and second sentences of paragraph 97.

Paragraph 98: The da Vinci queries the memory chip prior to performing any operations with the particular EndoWrist. After a certain number of uses the chip wipes itself and, because the da Vinci cannot identify the EndoWrist after the memory-wipe, the EndoWrist is rendered non-operational, based solely on the number of times it is attached to a da Vinci robot arm, without regard to the actual physical condition of the EndoWrist. A majority of EndoWrists have a maximum use limit of ten.

98. Intuitive admits that the da Vinci queries the programmed memory chip in the particular EndoWrist prior to performing any operations, but otherwise denies the allegations in the first sentence of paragraph 98. Intuitive admits that it has conducted rigorous testing and identified a maximum use limit for EndoWrists and that the maximum use limit ensures that instruments perform safely and reliably, but otherwise denies the allegations in the second sentence of paragraph 98. Intuitive denies the allegations in the third sentence of paragraph 98.

Paragraph 99: EndoWrists are a separate product from da Vincis themselves. Although the two are complementary products, there is demand for repair and replacement of EndoWrists separate from demand for da Vincis, and Intuitive sells replacement EndoWrists separately from da Vincis, in part because EndoWrists may wear out over time and need repair or replacement. Just as a car owner whose new tires wear down would not purchase a new car for its tires, but instead would either buy new tires or get her current tires retreaded, da Vinci owners do not purchase a new da Vinci with EndoWrists whenever their EndoWrists cease to be operative. Instead, they simply purchase replacement EndoWrists from Intuitive (since Intuitive effectively prevents repair of EndoWrists).

99. Intuitive denies the allegations in paragraph 99.

Paragraph 100: Intuitive's quotes for da Vinci robots typically do not include operating EndoWrists (they do sometimes include a small set of training instruments); EndoWrists are quoted using separate prices on a separate quote sheet. Moreover, da Vinci Sales Agreements specify that EndoWrists are to be purchased separately pursuant to the terms and conditions of instrument catalogs. To facilitate the sale of replacement EndoWrists, Intuitive has an EndoWrist sales division with its own personnel separate and apart from the sales division and personnel responsible for da Vincis.

100. Intuitive denies the allegations in the first and second sentences of paragraph 100. Intuitive admits that it has separate sales divisions for EndoWrists and da Vincis, but otherwise denies the allegations in the third sentence of paragraph 100.

Paragraph 101: Further demonstrating that the EndoWrist Repair and Replacement Aftermarket is a distinct product market from the market for da Vincis, there is independent demand for EndoWrist repair (as discussed in more detail below), which is provided as a standalone service by IRCs such as Restore, Rebotix, Revanix, and SIS.

101. Intuitive denies the allegations in paragraph 101.

Paragraph 102: Intuitive itself explicitly distinguishes between da Vincis and EndoWrists as separate products with separate revenue streams. A 2015 investor presentation created by

Intuitive, for example, identified Intuitive's "[e]xtensive instrument and accessory product line" as a distinct "Corporate Asset."⁴² (Intuitive consistently describes EndoWrists as comprising the majority of its "instrument" offerings, including in SEC filings and Endo Wrist/instrument catalogs.) The presentation also described Intuitive's plans to introduce "additional products," which other parts of the presentation make clear included new EndoWrists, for the already available Xi.⁴³ Intuitive has in fact repeatedly launched new EndoWrist products subsequent to the launch of the particular da Vinci model with which they are compatible, further highlighting how these are separate products. Moreover, Intuitive has sought and received FDA clearances for its EndoWrists separately from the clearance it has received for the da Vinci.

Footnote 42: Intuitive Investor Presentation Q3 2015, at 38.

Footnote 43: *Id.* at 37.

102. Intuitive denies the allegations in the first sentence of paragraph 102. Intuitive denies the allegations in the second, third, fourth and fifth sentences of paragraph 102 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein, except states that to the extent paragraph 102 purports to characterize an Intuitive investor presentation, Intuitive respectfully refers to that presentation for its full context and contents.

Paragraph 103: Intuitive's SEC filings also show that Intuitive recognizes EndoWrists and da Vincis as separate products. Under a header describing "Intuitive Surgical's Products and Services," for example, Intuitive's 10-K filed in March 2006 stated: "Our principal products include the da Vinci Surgical System and a variety of multiple-use EndoWrist instruments and accessories."⁴⁴ The same section goes on to describe the "da Vinci Surgical System" and its "components" separately from EndoWrists.⁴⁵ Intuitive also consistently distinguishes between its "recurring" revenue streams from EndoWrist sales and its one-time revenues from sales of da Vinci robots. For example, in its 10-K from March 2006, Intuitive stated, "After the initial sale of the da Vinci Surgical System into customer accounts, we generate recurring revenue as our customers use the da Vinci Surgical System to perform surgery and, in the process, buy and consume our EndoWrist instruments and accessory products."⁴⁶ The same document noted how Intuitive "launched several new instrument products during 2005, including the energy-based, monopolar shears and the harmonic shears"⁴⁷ In contrast, Intuitive described its software as "incidental" to the da Vinci as a whole and "not sold or marketed separately."⁴⁸

Footnote 44: Intuitive (Form 10-K), at 6 (Mar. 15, 2006)

Footnote 45: *Id.* at 6-7.

Footnote 46: *Id.* at 33.

Footnote 47: *Id.* at 34.

Footnote 48: *Id.* at 55

103. Intuitive denies the allegations in the first and fourth sentences of paragraph 103. Intuitive admits that in its 10-K for the year ended December 31, 2005, Intuitive stated under the

heading “Intuitive’s Surgical Products and Services” that “[o]ur principal products include the da Vinci Surgical System and a variety of multiple-use EndoWrist instruments and accessories,” but otherwise denies the allegations in the second sentence of paragraph 103. Intuitive admits that in its 10-K for the year ended December 31, 2005, Intuitive included under the heading “Intuitive’s Surgical Products and Services,” two subheadings: “da Vinci Surgical Systems” and “Endowrist Instruments and Intuitive Accessories,” but otherwise denies the allegations in the third sentence of paragraph 103. Intuitive admits that in its 10-K for the year ended December 31, 2005, Intuitive stated, “After the initial sale of the da Vinci Surgical System into customer accounts, we generate recurring revenue as our customers use the da Vinci Surgical System to perform surgery and, in the process, buy and consume our EndoWrist instruments and accessory products,” but otherwise denies the allegations in the fifth sentence of paragraph 103. Intuitive admits that in its 10-K for the year ended December 31, 2005, Intuitive stated, “We launched several new instrument products during 2005, including the energy-based, monopolar shears and the harmonic shears, which [Intuitive] codeveloped with Ethicon Endosurgery, Inc.,” but otherwise denies the allegations in the sixth sentence of paragraph 103. Intuitive admits that in its 10-K for the year ended December 31, 2005, Intuitive stated, “The Company’s da Vinci Surgical System, HERMES Control Center and AESOP Endoscope Positioner contain a software component. The Company believes that this software element is an incidental part of each system. The software element within the Company’s products is not sold or marketed separately to customers, and the software does not operate independently of each system,” but otherwise denies the allegations in the seventh sentence of paragraph 103.

Paragraph 104: The EndoWrist Repair and Replacement Aftermarket is significantly larger than either the primary da Vinci market or the da Vinci service aftermarket. Intuitive’s revenues from the sale of instruments and accessories in the U.S. totaled \$1.79 billion in 2019, and despite the Coronavirus pandemic, 2020 instrument and accessory revenues were an estimated \$1.785

billion.⁴⁹ By comparison, Intuitive reported revenues of \$830 million from robot sales and \$508 million from service contracts in 2019.⁵⁰

Footnote 49: Intuitive (Form 10-K), at 98 (Feb. 10, 2021).

Footnote 50: Intuitive (Form 10-K), at 87 (Feb. 7, 2020).

104. Intuitive denies the allegations in the first sentence of paragraph 104. Intuitive admits that in its 10-K for the year ended December 31, 2020, Intuitive reported revenues for the sale of instruments and accessories in the United States as \$1.79 billion in 2019 and \$1.785 billion in 2020, but otherwise denies the allegations in the second sentence of paragraph 104. Intuitive admits that in its 10-K for the year ended December 31, 2019, Intuitive reported revenues of \$830.7 million from the sales of da Vincis and \$508.4 million from services, but otherwise denies the allegations in the third sentence of paragraph 104.

Paragraph 105: Indeed, the vast majority of Intuitive's EndoWrist revenue and profit, and thus its overall revenue and profit, comes from the replacement of EndoWrists. This is because while a da Vinci represents a large initial investment for Intuitive's customers, they are typically in service for five years, if not a decade, while EndoWrists must be replaced, typically after a mere ten uses, thus providing Intuitive with a recurring revenue stream. Indeed, the bulk of Intuitive's revenue and profit growth over the last decade in the U.S. comes from its sale of its simple EndoWrists, not its complex, multi-million-dollar robots, as demonstrated by the revenue figures from Intuitive's 10-Ks from 2001 to 2020 below:⁵¹ [IMAGE]

Footnote 51: These charts reflect Intuitive's worldwide revenues; revenues by region are unavailable prior to 2017.

105. Intuitive denies the allegations in the first, second and third sentences of paragraph 105, except states that to the extent paragraph 105 purports to characterize and quote from Intuitive's 10-Ks for the years ended December 31, 2001 through December 31, 2020, Intuitive respectfully refers to those filings for their full context and contents.

Paragraph 106: Because of Intuitive's exclusionary conduct, the EndoWrist Repair and Replacement Aftermarket is dominated by Intuitive's sales of replacement EndoWrists rather than the servicing (i.e., cleaning, sharpening, or repairing) of EndoWrists that the da Vinci customers already own. The replacement EndoWrists sold by Intuitive and the EndoWrist repair services provided (or that could be provided) by IRCs are substitutable. For instance, hospitals hire Rebotix to inspect and repair EndoWrists by, for example, tightening the graspers or sharpening the scissors. And SIS entered into contracts with several hospitals and health care systems to provide EndoWrist repair services. More hospitals would substitute EndoWrist replacement from Intuitive with these services in the absence of Intuitive's exclusionary scheme.

106. Intuitive denies the allegations in the first and second sentences of paragraph 106. Intuitive denies the allegations in the third, fourth and fifth sentences of paragraph 106 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 107: Intuitive's Sales Agreements require hospitals to replace their EndoWrists exclusively with new EndoWrists purchased from Intuitive. Per these contracts, Intuitive has the right to void warranties associated with the da Vinci itself if unauthorized or unapproved instruments are used with the da Vinci. This causes hospitals to continually purchase replacement EndoWrists from Intuitive or risk voiding their service agreements for not just the serviced EndoWrist(s) but also the da Vinci itself.

107. Intuitive admits that the SLSA prohibits customers from engaging any unauthorized third party to repair, refurbish, or recondition EndoWrists at any time and provides Intuitive with the right to void warranties associated with the da Vinci if unauthorized instruments are used with the da Vinci, but otherwise denies the allegations in the first and second sentences of paragraph 107. Intuitive denies the allegations in the third sentence of paragraph 107 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 108: Intuitive's standard Sales Agreements tie the purchase or lease of a da Vinci to its "maximum number of uses" requirement for EndoWrists. The use requirement applies to every single EndoWrist, regardless of its condition or whether it could be used in additional procedures.

108. Intuitive denies the allegations in the first sentence of paragraph 108. Intuitive admits that it has conducted rigorous testing and identified a maximum use limit for EndoWrists and that the maximum use limit ensures that instruments perform safely and reliably, but otherwise denies the allegations in the second sentence of paragraph 108.

Paragraph 109: Before releasing its EndoWrists to market, Intuitive told the FDA that the EndoWrists and traditional instruments "are essentially identical . . . in terms of shape, size, function, and tissue effect"; "are substantially equivalent in intended use and/or method of operation"; and "demonstrate substantial equivalence . . . in terms of safety and effectiveness." The FDA agreed and "determined the [EndoWrist] device" is "substantially equivalent" to the

traditional devices. Instruments used in traditional laparoscopic surgeries are cleaned and inspected before and after each surgery and may be repaired between procedures, making them usable for hundreds of surgeries. Likewise, because EndoWrists and traditional instruments are similar in many ways, including as to their surgical ends, EndoWrists could be used for dozens—and in some cases over 100—procedures, if inspected and repaired as needed between surgeries.

109. Intuitive admits that it represented in its 510(k) filing for Endoscopic Instruments and Accessories filed on January 19, 1999, that (1) “[t]he Intuitive Surgical Instruments are essentially identical in terms of shape, size, function and tissue effect to the standard Class I and II endoscopic instruments cited”; (2) “[t]he Intuitive Surgical Endoscopic Instruments and Tools are substantially equivalent in intended use and/or method of operation” to certain predicate devices; (3) with respect to clinical study data, “[a]n extensive prospectively randomized and concurrently controlled clinical study was performed to demonstrate substantial equivalence to the predicate devices cited in terms of safety and effectiveness”; and (4) Intuitive “determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment of the Medical Device Amendment, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act,” but otherwise denies the allegations in the first and second sentences of paragraph 109. Intuitive denies the allegations in third sentence of paragraph 109 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the fourth sentence of paragraph 109.

Paragraph 110: The FDA permits servicing of approved medical devices by third parties, going so far as to conclude that “[t]he continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system.”⁵² In such cases, third-party service providers repair instruments to meet their original intended use without affecting the safety and effectiveness of the instrument or its indications for use. The instrument is maintained at, or returned to, its original safety and effectiveness. Indeed, the FTC recently quoted the FDA’s conclusion in a 2018 Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices that “the objective evidence indicates that many . . . third party entities provide high quality safe, and effective servicing of medical devices.”⁵³

Footnote 52: FDA Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices (May 2018), at i, available at <https://www.fda.gov/media/113431/download> (last visited on September 10, 2021).

Footnote 53: Nixing the Fix: An FTC Report to Congress on Repair Restrictions (May 2021), at 51, n.284 (quoting FDA Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices (May 2018)), available at [https://www.ftc.gov/system/files/documents/reports/nixing-fix-ftcreport-congress-repair-restrictions/nixing the fix report final 5521 630pm-508 002.pdf](https://www.ftc.gov/system/files/documents/reports/nixing-fix-ftcreport-congress-repair-restrictions/nixing%20the%20fix%20report%20final%205521%20630pm-508%20002.pdf) (last visited on September 10, 2021).

110. Intuitive denies the allegations in the first sentence of paragraph 110, except states that to the extent paragraph 110 purports to characterize and quote from a May 2018 FDA report, Intuitive respectfully refers to that article for its full context and contents. Intuitive denies the allegations in the second sentence of paragraph 110 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the third sentence of paragraph 110, except states that to the extent paragraph 110 purports to characterize and quote from a May 2018 FTC report, Intuitive respectfully refers to that article for its full context and contents.

Paragraph 111: After undergoing third-party service, EndoWrists have passed third-party simulated life-testing to 50 or more additional uses. This is consistent with the fact that EndoWrists used for training purposes commonly last for well over 100 uses, as described below. However, Intuitive takes active measures to preclude EndoWrists from having this longevity for its customers.

111. Intuitive denies the allegations in the first and second sentences of paragraph 111 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the third sentence of paragraph 111.

Paragraph 112: As shown below in Figure 5, EndoWrists are in many respects nearly indistinguishable from manually operated surgical tools. Both are made from medical grade materials, such as stainless steel and composites, that typically last through hundreds of surgeries.⁵⁴ Figure 5 includes an EndoWrist on the left and a traditional, manually manipulated tool on the right, and illustrates that their surgical ends are nearly identical.

Footnote 54: Rebotix Complaint ¶ 39.

Figure 5: EndoWrist forceps v. Traditional manual forceps [IMAGES]

112. Intuitive denies the allegations in the first sentence of paragraph 112. Intuitive

admits that EndoWrists are constructed using medical grade materials, including stainless steel and composites, but otherwise denies the allegations in the second sentence of paragraph 112 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein, except states that to the extent paragraph 112 purports to characterize Rebotix's complaint, Intuitive respectfully refers to Intuitive's Answer to Rebotix's Complaint (ECF No. 60) for Intuitive's responses to the cited allegations. Intuitive admits that the image on the left of Figure 5 is an EndoWrist, but otherwise denies the allegations in the third sentence of paragraph 112.

Paragraph 113: However, despite being "substantially equivalent" to traditional laparoscopic instruments, Intuitive limits most EndoWrists to just ten uses, dramatically fewer than their manually operated counterparts.

113. Intuitive admits that it has conducted rigorous testing and identified a maximum use limit for EndoWrists and that the maximum use limit ensures that instruments perform safely and reliably, but otherwise denies the allegations in paragraph 113 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 114: To enforce this arbitrary restriction, Intuitive installs memory chips in its EndoWrists that ostensibly count the number of "uses," though, as discussed above, the chip actually counts the number of times the EndoWrist is simply attached to a da Vinci robot arm, rather than its actual use. Intuitive has exclusive control over the use counter, and once the counter hits its limit, the chip renders the EndoWrist non-functional by wiping its memory so that the EndoWrist can no longer communicate with the da Vinci. Intuitive has designed the EndoWrists to prevent the use counter from being bypassed or reset.

114. Intuitive admits that it includes a programmed memory chip in each EndoWrist that, among other functions, counts the number of uses, but otherwise denies the allegations in first sentence of paragraph 114. Intuitive admits that it has conducted rigorous testing and identified a maximum use limit for EndoWrists and that the maximum use limit ensures that instruments perform safely and reliably, but otherwise denies the allegations in the second sentence of paragraph 114. Intuitive admits the allegations in the third sentence of paragraph

Paragraph 115: The maximum use requirement for EndoWrists is not based on safety or effectiveness considerations. First, Intuitive has never provided its customers or the FDA any clinical or scientific data to support its use limits; Intuitive’s own instrument catalogs demonstrate that the useful lives of the EndoWrists are much longer than their use limits. Yet irrespective of the actual condition of the EndoWrist once it hits ten uses, it must be replaced without exception. Second, Intuitive described the EndoWrist to the FDA as possessing substantial equivalence in terms of safety and effectiveness to its manually manipulated counterparts, which have no predetermined use limits. Third, when Intuitive sells EndoWrists for training purposes, the use limits are much higher than the exact same tools sold for surgical use, with no demonstrable or practical difference between the two. Nor does the surgical equipment industry distinguish between an instrument sold for clinical use and the same instrument sold for training use. Training instruments, like instruments for clinical use, must retain their functionality for the surgeon during use. The only difference is the generation of revenue for the hospital on a surgical procedure for an instrument in clinical use. Indeed, whereas Intuitive places an artificial use limit of ten on many EndoWrists, Intuitive employees conducting training sessions have used these same EndoWrists 100 to 150 times without issue. Intuitive has stated that the maximum use requirement allows Intuitive to “sell the instrument for a fixed number of uses or hours and effectively price our EndoWrist instruments on a per-procedure or per-hour basis,” but there are no medical necessity or patient welfare concerns motivating Intuitive’s use caps; rather, the use limits reflect Intuitive’s desire and ability to charge supracompetitive prices.⁵⁵

Footnote 55: See Intuitive (Form 10-K), at 6 (March 30, 2001).

115. Intuitive denies the allegations in the first, second, seventh, eighth and ninth sentences of paragraph 115. Intuitive admits that it has conducted rigorous testing and identified a maximum use limit for EndoWrists and that the maximum use limit ensures that instruments perform safely and reliably, but otherwise denies the allegations in the third sentence of paragraph 115. Intuitive admits that it represented in its 510(k) filing for Endoscopic Intuitive Instruments and Accessories filed on January 19, 1999, that: “[t]he Intuitive Surgical Instruments are essentially identical in terms of shape, size, function and tissue effect to the standard Class I and II endoscopic instruments cited”; “[t]he Intuitive Surgical Endoscopic Instruments and Tools are substantially equivalent in intended use and/or method of operation” to certain predicate devices; with respect to clinical study data, “[a]n extensive prospectively randomized and concurrently controlled clinical study was performed to demonstrate substantial equivalence to

the predicate devices cited in terms of safety and effectiveness”; and Intuitive “determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment of the Medical Device Amendment, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act,” but otherwise denies the allegations in the fourth sentence of paragraph 115. Intuitive admits that it has set higher limits regarding the number of times certain EndoWrists can be used when they are used for training than when they are used for clinical purposes, but otherwise denies the allegations in the fifth sentence of paragraph 115. Intuitive denies the allegations in the sixth sentence because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive admits that its 10-K for the year ended December 31, 2000 stated that Intuitive “can sell the instruments for a fixed number of uses or hours and effectively price our EndoWrists on a per-procedure basis or per-hour basis,” but otherwise denies the allegations in the tenth sentence of paragraph 115.

Paragraph 116: Use limits are not based on any FDA regulations. The surgical instruments used with Asensus’ Senhance do not have use limits. Traditional laparoscopic instruments do not have use limits.

116. Intuitive denies the allegations in the first sentence of paragraph 116. Intuitive denies the allegations in the second and third sentences of paragraph 116 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 117: As recently as November 12, 2020, Intuitive submitted a 510(k) premarket notification summary to the FDA for several EndoWrists. The summary does not reference any clinical or scientific data showing that the EndoWrists lose their functionality after reaching the ten-use limit. Nor did Intuitive indicate that EndoWrists could not be serviced or repaired to make them safe and effective after reaching the ten-use limit.

117. Intuitive admits that it submitted a 510(k) application to the FDA for the da Vinci SP Surgical System, Model SP1098, EndoWrist SP Instruments and Accessories with the 510(k)

number K202571, but otherwise denies the allegations in the first sentence of paragraph 117. Intuitive admits that the 510(k) premarket notification summary for 510(k) number K202571 states, “Based on the intended use, indications for use, technological characteristics and performance data, the Intuitive Surgical da Vinci SP® Surgical System, Model SP1098, EndoWrist SP™ Instruments, and Accessories, including the SP Access Port Kit, have been assessed and found to be substantially equivalent (SE) to the predicate devices. This SE determination is based on performance testing that included: bench testing, cadaver and animal testing with simulated and representative urologic surgical procedures, and a human factors evaluation,” but otherwise denies the allegations in the second and third sentences of paragraph 117.

Paragraph 118: Customers cannot predict their costs for EndoWrists. Intuitive has complete control over EndoWrist use limits and can (and has) changed the use limits and instructions for use unilaterally and without notice. For example, Intuitive issued instructions for use (“IFU”) for EndoWrists, setting a maximum number of autoclave cycles, which sterilize the EndoWrists using steam pressure. Because of the way that da Vinci surgeries are prepped and performed, EndoWrists must often undergo an autoclave cycle even if not actually attached to a robot during surgery. The specified limit on autoclave cycles is extremely low compared to comparable devices made of similar medical grade materials. These unilateral changes can require early replacement, even if the counter has not hit its maximum use limit. They also substantially increase (a) the per-surgery cost of EndoWrists to hospitals, and (b) Intuitive’s supracompetitive EndoWrist profits, without prior notice to hospitals. Intuitive, as the sole manufacturer of EndoWrists, exercises complete control over EndoWrist replacement prices. Thus, customers cannot reasonably predict the timing or pricing for replacing EndoWrists.

118. Intuitive denies the allegations in the first, fourth, fifth, sixth and ninth sentences in paragraph 118 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the second, seventh and eighth sentences in paragraph 118. Intuitive admits that it has issued an IFU for EndoWrists setting a maximum number of autoclave cycles, as required by the FDA, but otherwise denies the allegations in the fourth sentence of paragraph 118.

Paragraph 119: Intuitive has imposed arbitrary technological barriers that prevent IRCs and others (such as manufacturers) from entering and/or competing effectively in the EndoWrist Repair and Replacement Aftermarket. For instance, in addition to the use counter, Intuitive requires that any surgical instrument attached to the da Vinci have a serial number generated by Intuitive, which Intuitive does not provide to third parties. Because surgical instruments are necessary to perform surgery, Intuitive's design means that customers must purchase EndoWrists to perform surgeries using the da Vinci. Intuitive's serial number requirement effectively forecloses third parties from manufacturing substitutes for EndoWrists.

119. Intuitive denies the allegations in paragraph 119.

Paragraph 120: Surgical instrument refurbishment is commonly relied on by hospitals and surgery centers. According to an FDA report from 2018, thousands of firms offered medical device maintenance,⁵⁶ and market experts estimate the global market generates between \$28.97 billion⁵⁷ and \$35.3 billion⁵⁸ in revenue annually. Not only is this market sizable, it is indispensable to the healthcare industry in this country. According to the FDA, the "continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system," and third party entities "provide high quality, safe, and effective servicing of medical devices."⁵⁹ Within the broad medical device maintenance and repair space, the maintenance of surgical instruments is expected to see the highest annual growth rate in coming years, according to one market research service.

Footnote 56: FDA Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices (May 2018), at 19, available at <https://www.fda.gov/media/113431/download> (last visited on September 10, 2021).

Footnote 57: <https://www.marketsandmarkets.com/Market-Reports/medical-equipment-maintenancemarket-69695102.html> (last visited on September 10, 2021)

Footnote 58: <https://www.grandviewresearch.com/industry-analysis/medical-equipment-maintenance-market>

(last visited on September 10, 2021)

Footnote 59: FDA Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices (May 2018), at i, available at <https://www.fda.gov/media/113431/download> (last visited on September 10, 2021).

120. Intuitive denies the allegations in the first and third sentences of paragraph 120 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the second sentence of paragraph 120 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein, except states that to the extent the second, fourth and fifth sentences in paragraph 120 purports to characterize and quote from a May 2018 FDA report, a "Markets and Markets" article and a "Grand View Research," Intuitive respectfully refers to those articles for

their full context and contents.

Paragraph 121: IRCs possess the ability to service EndoWrists to prolong their use. For example, Rebotix has invested substantial time, resources, and money (millions of dollars) to develop the Rebotix Interceptor, which resets the use counter in at least some EndoWrists. The Interceptor only resets the use count; it does not interfere with any other communications the da Vinci has with the EndoWrist. The safety and functionality of the EndoWrist, including communication between the EndoWrist and the da Vinci, are therefore not disturbed. Even in its hobbled state, caused by Intuitive's iron grip, Rebotix provides hospitals with savings of approximately 40% on their EndoWrist expenses. However, as discussed below, see § A.3.c, because of anticompetitive countermeasures Intuitive employs, the Interceptor has limited applicability as it does not work with the newer Xi model.

121. Intuitive denies the allegations in paragraph 121.

Paragraph 122: As discussed above, see, e.g., paragraphs 77-89, Restore specializes in servicing da Vincis and EndoWrists, and hires da Vinci-certified field service engineers with prior training and experience at Intuitive. Restore has been servicing EndoWrists since 2018. While Restore can reset the use counter on EndoWrists for the Si robot, it pays a large licensing fee for the technology to do so. Restore passes these costs on to its customers in the form of at least 20% higher service fees. Still, Restore offers repair (including use-counter reset) rates that are at least 25% on average below the replacement EndoWrist prices offered by Intuitive. Like Rebotix, and again, because of anticompetitive countermeasures taken by Intuitive, Restore cannot reset the use counter for other da Vinci models, including the X and Xi robots. But for the anticompetitive conduct of Intuitive, Restore would be able to offer even lower repair rates and repair services on many more EndoWrists.

122. Intuitive admits that Restore has hired former Intuitive personnel in the past, but otherwise denies the allegations in paragraph 122.

Paragraph 123: SIS is a veteran of the medical device maintenance industry that recently has made efforts to enter the EndoWrist Repair and Replacement Aftermarket. SIS has 50 years of experience servicing surgical instruments and equipment, ranging from simple devices such as forceps and scalpels to complex electromechanical devices such as flexible video endoscopes, powered orthopedic devices, and surgical video systems. In recent years, SIS created a program for the inspection and repair of EndoWrists. SIS's repair procedures include an initial disassembly and inspection, checking the mechanical operation and integrity of all mechanical components; an electrical integrity check to confirm electrical insulation, cleaning, sharpening, or alignment of the instrument tip; and a series of tests to confirm that all the movements of the instrument tip are within original specifications. SIS also sets the use counter to a value corresponding to the initial setting of a new EndoWrist. These procedures are similar to procedures that SIS has performed for decades on dozens of types of surgical instruments and medical devices of similar or greater complexity.

123. Intuitive denies the allegations in paragraph 123 because it is without knowledge

or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 124: SIS states that it has the personnel, facilities, equipment, and experience to service at least 1,500 EndoWrists per month to prolong their use. In fact, SIS states it has already serviced and repaired EndoWrists that have since been used successfully and without incident in da Vinci surgeries. SIS also claims that independent testing shows that instruments serviced by SIS are suitable for at least 50 uses.

124. Intuitive denies the allegations in paragraph 124 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 125: SIS's initial foray into the EndoWrist Repair and Replacement Aftermarket was successful. Although SIS did not contact potential customers until 2019, by 2020 SIS expected tens of millions of dollars in sales for the repair of EndoWrists. SIS had obtained and was in the process of repairing EndoWrists from some of its initial customers before Intuitive began pressuring those customers to abandon their efforts to secure the cost savings offered by SIS.

125. Intuitive denies the allegations in the first sentence of paragraph 125. Intuitive denies the allegations in the second and third sentences of paragraph 125 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 126: Despite the IRCs' efforts described above, Intuitive has maintained a market share in the EndoWrist Repair and Replacement Aftermarket of well over 95% for nearly 20 years.

126. Intuitive denies the allegations in paragraph 126.

Paragraph 127: Intuitive is the sole manufacturer of EndoWrists worldwide and is the only seller of EndoWrists in the U.S. U.S.-based IRCs such as Restore, Rebotix, Revanix, and SIS have the capability to service EndoWrists throughout the U.S.

127. Intuitive admits that it manufactures EndoWrists and sells EndoWrists in the United States. Intuitive denies the remaining allegations in paragraph 127 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 128: EndoWrists are the only surgical instruments that are compatible with and FDA- approved for use with the da Vinci, making them the only surgical instruments available for use with the da Vinci in the U.S.

128. Intuitive admits that EndoWrists used with da Vincis have received FDA clearance, but otherwise denies the allegations in paragraph 128.

Paragraph 129: U.S. hospitals are thus unable to buy EndoWrists, or potentially substitutable instruments, from suppliers in other countries, even though Intuitive sets its EndoWrist prices above competitive levels.

129. Intuitive denies the allegations in paragraph 129 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 130: Intuitive contractually ties its provision of da Vincis, and service of the robot, to a customer's agreement to purchase new EndoWrists from Intuitive as the exclusive means to continue using the customer's da Vinci (i) if and when the customer's EndoWrists fall out of perfect condition and, in any event, (ii) once the customer's EndoWrists reach their arbitrary use limits. Intuitive generally includes these contractual provisions in the Sales Agreements for its da Vinci. These provisions combine to restrict competition in the EndoWrist Repair and Replacement Aftermarket and thereby dramatically increase the number and price of new EndoWrists Intuitive's customers must buy from Intuitive.

130. Intuitive denies the allegations in paragraph 130.

Paragraph 131: Intuitive's Sales Agreements for the da Vinci expressly prohibit its customers from performing repairs on EndoWrists—for example, sharpening the scissors or aligning the graspers. In other words, customers must commit to purchasing replacement EndoWrists from Intuitive (rather than EndoWrist service from third parties). The service agreement for the da Vinci—which often is combined with the Sales Agreements—similarly provides that if any third party repairs the EndoWrists, Intuitive no longer is obligated to service the da Vinci itself. In addition, under the service agreement, any third-party service on an EndoWrist voids Intuitive's one-year warranty not just on that EndoWrist but on the da Vinci as well.

131. Intuitive admits that the SLSA prohibits customers from performing any unauthorized repair of EndoWrists, but otherwise denies the allegations in the first and second sentences of paragraph 131. Intuitive admits that the SLSA prohibits customers from engaging any unauthorized third party to repair, refurbish, or recondition EndoWrists at any time, but otherwise denies the allegations in the third sentence of paragraph 131. Intuitive denies the allegations in the fourth sentence of paragraph 131.

Paragraph 132: Intuitive's Sales Agreements further tie the purchase or lease of a da Vinci to the "maximum number of uses" requirement for EndoWrists. Those Sales Agreements provide that the customer "purchases" any instruments for use with the da Vinci from Intuitive, and require that the customer use those instruments only for the "maximum number of uses" set forth in the instrument catalog. These provisions require customers whose EndoWrists have reached their "maximum number of uses" to purchase new EndoWrists—regardless of whether the used EndoWrists are in perfect condition or could be returned to such condition through routine

repairs. During the relevant time period, the most common use limit for EndoWrists was ten. But the safe and usable life of EndoWrists far exceeds the maximum number of uses designated by Intuitive. For example, forceps that are periodically inspected and, if necessary, aligned or adjusted can still be in perfect condition after well over 100 uses. But, because of Intuitive's Sales Agreements, hospitals are contractually obligated to buy far more (ten to twenty times as many) EndoWrists from Intuitive than they actually would need if the restrictive tying clause were eliminated. The clause prevents hospitals from using the services of third-party service providers (such as the IRCs) to safely extend the life of their EndoWrists beyond the use limits arbitrarily set by Intuitive.

132. Intuitive denies the allegations in the first, second, fourth, fifth, sixth, seventh and eighth sentences of paragraph 132. Intuitive admits that the SLSA prohibits customers from engaging any unauthorized third party to repair, refurbish, or recondition EndoWrists at any time, but otherwise denies the allegations in the third sentence of paragraph 132.

Paragraph 133: Intuitive has also acted with the clear intent to limit competition in the EndoWrist Repair and Replacement Aftermarket through its design of the EndoWrist itself, including features solely intended to exclude competitors from the EndoWrist Repair and Replacement Aftermarket. These features allow Intuitive to maintain its monopoly and cause Intuitive's customers to pay exorbitant sums to Intuitive for brand new EndoWrists they do not yet need.

133. Intuitive denies the allegations in paragraph 133.

Paragraph 134: For example, as discussed above, in order to enforce the "maximum number of uses" requirement for EndoWrists, Intuitive includes a programmed memory chip in each EndoWrist that counts the number of times the EndoWrist is attached to a da Vinci, and then renders the EndoWrist non-functional after an Intuitive-specified number of uses. After the memory chip reaches the count determined by Intuitive, the memory chip is wiped, preventing the EndoWrist from communicating with the da Vinci and rendering the instrument inoperable. This memory-wipe causes Intuitive customers to discard EndoWrists and purchase new ones after a given number of uses—usually ten—even when the EndoWrists are maintained at or better than their original levels of safety and effectiveness. Conceding that the design of the use-activated chip memory-wiper is intended as an enforcement mechanism for its contractual ties, Intuitive has stated in a filing with this Court that "the instruments were always designed to ensure compliance with [Intuitive]'s usage limits." Intuitive's Reply Mem. of Law in Support of Its Mot. To Dismiss (Sept. 3, 2021) (ECF No. 57), at 5, *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC.

134. Intuitive admits that it includes a programmed memory chip in each EndoWrist that, among other functions, counts the number of uses, but otherwise denies the allegations in the first sentence of paragraph 134. Intuitive admits that it has conducted rigorous testing and

identified a maximum use limit for EndoWrists and that the maximum use limit ensures that instruments perform safely and reliably, but otherwise denies the allegations in the second sentence of paragraph 134. Intuitive denies the allegations in the third sentence of paragraph 134. Intuitive admits that in its Reply Memorandum of Law in Support of Its Motion to Dismiss the Complaint in *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC, Intuitive stated, “[i]n other words, Rebotix could not allege that Intuitive ‘redesigned’ its instruments to thwart third-party ‘repairs’; rather, the instruments were always designed to ensure compliance with the usage limits—which Rebotix and other third-party ‘repair’ entities (like SIS) have attempted to circumvent,” but otherwise denies the allegations in fourth sentence of paragraph 134.

Paragraph 135: The use-triggered memory-wipe of EndoWrists is not based on considerations of safety or effectiveness. All components of the EndoWrists are medical-grade materials that are capable of many times the number of uses permitted by Intuitive. The memory chip does not monitor the safety or durability of EndoWrists—the chip does not, for example, determine whether components of the EndoWrist have become unresponsive to requested movement. Instead, the memory chip tracks only the number of times the EndoWrist is attached to a da Vinci robot arm. Through the memory-wipe function of this memory chip, Intuitive causes EndoWrists to become inoperable long before they otherwise would wear out. This planned obsolescence severely inhibits competition for EndoWrist repairs and enables Intuitive to extract additional profits from its customers, who as a consequence must buy additional EndoWrists at supracompetitive prices.

135. Intuitive denies the allegations in the first, second, fifth and sixth sentences of paragraph 135. Intuitive admits that it includes a programmed memory chip in each EndoWrist that, among other functions, counts the number of uses, but otherwise denies the third and fourth sentences of paragraph 135.

Paragraph 136: The use limits are not based on any FDA or other regulatory requirement. As set forth above, Intuitive’s premarket notifications to the FDA for the EndoWrists represented to the FDA that they were “essentially identical” to their precursor traditional laparoscopic instruments, which did not include any use limits, and which can safely be used for more than 100 surgeries. The FDA approved the EndoWrists on that basis.

136. Intuitive denies the allegations in the first and third sentences of paragraph 136.

Intuitive admits that it represented in its 510(k) filing for Endoscopic Instruments and Accessories filed on January 19, 1999, that (1) “[t]he Intuitive Surgical Instruments are essentially identical in terms of shape, size, function and tissue effect to the standard Class I and II endoscopic instruments cited”; (2) “[t]he Intuitive Surgical Endoscopic Instruments and Tools are substantially equivalent in intended use and/or method of operation” to certain predicate devices; (3) with respect to clinical study data, “[a]n extensive prospectively randomized and concurrently controlled clinical study was performed to demonstrate substantial equivalence to the predicate devices cited in terms of safety and effectiveness”; and (4) Intuitive “determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment of the Medical Device Amendment, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act,” but otherwise denies the allegations in the second sentence of paragraph 136.

Paragraph 137: Intuitive’s standard contracts and instrument catalogs do not refer to any regulatory requirement mandating use limits.

137. Intuitive admits that its SLSAs with customers and instrument catalogs do not describe the regulatory framework governing the design and use of EndoWrists, but otherwise denies the allegations in paragraph 137.

Paragraph 138: The use limits are not based on any clinical or scientific determination of the useful life of the instruments. Intuitive has not released to the public, nor does it provide to its customers, any clinical data that supports its EndoWrist use limits. In addition, analogous surgical instruments used by other surgical robots do not have use limits. For example, the TransEnterix Senhance robot discussed above uses surgical instruments that are substantially the same as Intuitive’s EndoWrists, but do not have arbitrary, contractually- or technologically-imposed use limits.

138. Intuitive denies the allegations in the first sentence of paragraph 138. Intuitive admits that it does not release to the public nor share with its customers the confidential clinical

data that supports the EndoWrist use limits, but otherwise denies the allegations in the second sentence of paragraph 138. Intuitive denies the allegations in the third and fourth sentences of paragraph 138 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 139: Moreover, doctors and hospitals who have used EndoWrists beyond their programmed use limits (i.e., after being inspected and repaired by IRCs who also reset the memory chip's use counter) report that the EndoWrists perform as well as when they were new.

139. Intuitive denies the allegations in paragraph 139 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 140: Intuitive has in fact admitted that the artificially limited lifespan of EndoWrists is intended to boost Intuitive's recurring revenue. During a 2005 presentation and Q&A session, Lonnie Smith, then Intuitive's CEO, discussed the ten-use limit on EndoWrists and touted the resulting recurring revenue streams it generated for Intuitive. Asked what made the EndoWrists usable only ten times, Smith responded that "part of it was, is to make it economically feasible as a company, I mean viable as a company because one of our competitors, our competitor, the one that failed, had very little recurring revenue stream, almost none And so it was part of our business model as well."⁶⁰ Intuitive has similarly called its da Vinci business model a "razor/razor blade" model, with recurring revenues from replacement EndoWrists being a key revenue driver, similar to how razor manufacturers generate far greater revenue on replacement blades than on the razors themselves. In sharp contrast to razor manufacturers, though, Intuitive possesses monopoly power in the market for minimally invasive surgical robots and has leveraged that monopoly power in the primary market to insulate itself from competition in the complementary consumables aftermarket. And, as detailed above, Intuitive has been successful in executing on this strategy: thanks to its exclusionary conduct, a growing majority of Intuitive's revenue (today, close to 60%) is derived from sales of the comparatively simple EndoWrists.

Footnote 60: Lonnie Smith, *From Start-up to Market Dominance in the Field of Surgical Robotics*, Entrepreneurial Thought Leaders (2005), <https://ecorner.stanford.edu/podcasts/from-start-up-to-market-dominance-in-the-field-of-surgical-robotics/> (last visited on September 10, 2021).

140. Intuitive denies the allegations in the first, fourth, fifth and sixth sentences of paragraph 140. Intuitive denies the allegations in the second and third sentences of paragraph 140, except states that to the extent paragraph 140 purports to characterize and quote from an interview and Q&A session by Entrepreneurial Thought leaders, Intuitive respectfully refers to that recording for its full context and contents.

Paragraph 141: Even though IRCs such as SIS, Restore, and Rebotix have the expertise to enter the EndoWrist Repair and Replacement Aftermarket, Intuitive has designed both the da Vinci and EndoWrists to inhibit the ability of these IRCs to compete in that Aftermarket.

141. Intuitive denies the allegations in paragraph 141.

Paragraph 142: Intuitive's intentional EndoWrist design choice to use a memory-wipe triggered by an Intuitive-set number of uses has caused SIS, Restore, and Rebotix to invest significant time and resources to develop various means to attempt to overcome the anticompetitive barriers Intuitive had built and compete in the EndoWrist Repair and Replacement Aftermarket.

142. Intuitive denies the allegations in paragraph 142.

Paragraph 143: Intuitive has re-designed its memory chip to strengthen its exclusionary technological ties in EndoWrists compatible with its newer X and Xi model da Vincis, and is in the process of using its monopoly power in the market for minimally invasive surgical robots and the da Vinci service aftermarket to cause customers to transition to the newer models. The solutions discovered by Restore and Rebotix to overcome the anticompetitive barriers Intuitive had built work only for EndoWrists used with the older da Vinci models (the S and Si models), not the newer, X and Xi models. Intuitive invested substantial resources and excessive efforts to re-design the memory chip installed in EndoWrists for the X and Xi models solely to prevent any third parties (including SIS, Restore and Rebotix) from servicing EndoWrists, to the detriment of Class members. There is no technical or safety justification for these changes. The anticompetitive intent behind these changes is further demonstrated by the fact that Intuitive had received reports by or before 2012—well before the launch of the Xi in 2014 or the X in 2017—that hospitals were circumventing the memory-wiper on EndoWrists and using them beyond Intuitive's arbitrary preprogrammed use limits.

143. Intuitive denies the allegations in paragraph 143.

Paragraph 144: Intuitive has further withdrawn its support for certain S and Si instruments and announced, in writing, its intention to discontinue production of all S and Si instruments and technical support for the da Vinci S and Si models in 2023. In this way, Intuitive is forcing its customers to switch to the da Vinci X and Xi models. Intuitive also raised the prices for some EndoWrists with the introduction of the X and Xi models.

144. Intuitive admits that it is gradually phasing out S and Si instruments, as well as service and technical support for da Vinci S and Si systems, but otherwise denies the allegations in the first sentence of paragraph 144. Intuitive denies the allegations in the second and third sentences of paragraph 144.

Paragraph 145: As discussed above, Intuitive has unilaterally changed functional counter values for certain EndoWrists by, among other things, changing the IFU for EndoWrists to cause early replacement, even if the (already arbitrary) use limit has not been reached. For instance, Intuitive

issued an IFU for EndoWrists setting a maximum number of autoclave cycles. Because of the way that da Vinci surgeries are prepped and performed, EndoWrists often have to undergo an autoclave cycle even if not actually attached to a robot during surgery. The specified limit on autoclave cycles is extremely low compared to comparable devices made of similar medical grade materials. These unilateral changes substantially increase the per-surgery cost of EndoWrists to hospitals, and Intuitive's supracompetitive EndoWrist profits, without prior notice to hospitals. And, because Intuitive does not provide hospitals any option for repair of the EndoWrist after the maximum number of autoclave cycles or use limit has been reached, Intuitive's unilateral changes to the IFU narrow the window in which IRCs may repair EndoWrists before the memory-wipe renders them inoperable.

145. Intuitive admits that it has changed the instructions for use, but otherwise denies the allegations in the first sentence of paragraph 145. Intuitive admits that it has issued an IFU for EndoWrists setting a maximum number of autoclave cycles, as required by the FDA, but otherwise denies the allegations in the second sentence of paragraph 145. Intuitive denies the allegations in the third and fourth sentences of paragraph 145 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the fifth and sixth sentences of paragraph 145.

Paragraph 146: Intuitive actively monitors the EndoWrist Repair and Replacement Aftermarket to ensure its monopoly remains uninterrupted and its customers continue to buy EndoWrists they would not yet need but for Intuitive's anticompetitive behavior. If a customer or IRC services an EndoWrist so that it can be used beyond Intuitive's arbitrarily set maximum use limit, Intuitive sends a letter demanding that they cease and desist from resetting the memory chip.

146. Intuitive denies the allegations in paragraph 146.

Paragraph 147: For example, when hospitals hire IRCs to repair their EndoWrists rather than purchase new ones, Intuitive representatives threaten to withhold maintenance services from the hospital should it continue to make such repairs rather than purchase more EndoWrists. Similarly, when a hospital uses an EndoWrist beyond the limit set by Intuitive, Intuitive threatens to withhold maintenance services for the hospital's da Vincis.

147. Intuitive denies the allegations in paragraph 147.

Paragraph 148: Intuitive's threats and tactics have succeeded. In large part as a result of Intuitive's anticompetitive conduct, hospitals are dependent on robot maintenance services for the continued operation of their da Vincis. The services include "provid[ing] and install[ing] Software upgrades"; "replac[ing] defective malfunctioning System parts"; and "replac[ing] and install[ing] Software, Hardware, and mechanical parts for safety." Each of these services can be obtained only from Intuitive. And if these services are not provided—e.g., if a malfunctioning

part is not replaced or the Software is not up-to-date—the da Vinci will display a “NEEDS SERVICE” warning message on the display panel. Doctors will not perform a surgery with a machine indicating that it “NEEDS SERVICE.” Nor will patients allow themselves to be operated upon by a machine that “NEEDS SERVICE.” Accordingly, when service is needed, the da Vinci is effectively rendered useless until service is provided. Hospitals cannot afford to have useless da Vincis. Da Vincis are large capital investments, and ongoing da Vinci surgeries are necessary to recoup that investment. Functional da Vincis also are necessary to maintain the goodwill of the doctors and patients who have scheduled minimally invasive robotic surgeries.

148. Intuitive denies the allegations in the first sentence of paragraph 148. Intuitive admits that the da Vinci will display a “NEEDS SERVICE” message on the display panel until needed services—including replacing a malfunctioning part or updating software—are rendered, but otherwise denies the allegations in paragraph 148 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations herein.

Paragraph 149: Intuitive has also attempted to scare potential competitors out of the EndoWrist Repair and Replacement Aftermarket. On or about February 12, 2019, Intuitive sent a cease-and-desist letter to Restore, demanding that it “immediately cease and desist” from “contacting Intuitive’s customers to offer service related to Intuitive’s products” and resetting EndoWrist use counters. Intuitive also has sent letters to Rebotix’s customers, threatening to withhold necessary contractual maintenance if a hospital uses Rebotix’s EndoWrist repair services. This would render the da Vinci useless. Further, after learning that its customers had entered into service contracts with SIS, Intuitive sent letters threatening to render the surgical robot inoperable and falsely claiming that using repaired EndoWrists would violate FDA requirements and intellectual property rights. SIS alleges that as a result of Intuitive’s threats, all of its customers backed out of their service agreements with SIS.

149. Intuitive denies the allegations in the first sentence of paragraph 149. Intuitive admits that on or about February 12, 2019, it sent a letter to Restore Robotics LLC demanding that Restore Robotics LLC cease and desist from, among other things, “marketing and offering a servicing process in the course of which the use counter of Endo Wrist® instruments’ memory device is manipulated and/or replaced to permit more than ten uses” or “contacting Intuitive’s customers to offer services related to Intuitive’s products,” but otherwise denies the allegations in the second sentence of paragraph 149. Intuitive admits that it sent letters to certain customers concerning their use of unauthorized services on instruments, but otherwise denies the

allegations in the third sentence of paragraph 149. Intuitive denies the allegations in the fourth and fifth sentences of paragraph 149. Intuitive denies the allegations in the sixth sentence of paragraph 149 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 150: Intuitive's anticompetitive conduct enables it to charge its customers supracompetitive prices that are independent of and far exceed the cost of EndoWrists. For example, as previously noted, Restore claims that Intuitive charges at least 25% higher prices on average for EndoWrist replacement compared with EndoWrist repairs by IRCs.

150. Intuitive denies the allegations in the first sentence of paragraph 150. Intuitive denies the allegations in paragraph 150 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 151: As a result of its exclusionary scheme, Intuitive can and does charge supracompetitive prices to replace EndoWrists at significantly higher costs than offered by IRCs to service EndoWrists for prolonged use.

151. Intuitive denies the allegations in paragraph 151.

RESPONSE TO "B. INTUITIVE'S ANTICOMPETITIVE CONDUCT INJURED PLAINTIFFS AND THE PROPOSED CLASS."

Paragraph 152: The da Vinci repair services and replacement of EndoWrists provided by Intuitive are substitutable with the da Vinci and EndoWrist repair services provided (or that could be provided) by IRCs, such that being able to hire IRCs could save hospitals a significant amount of money. However, due to the exclusionary service and EndoWrist replacement commitments Intuitive tied and ties to the purchase or lease of the da Vinci, these substitute services are typically not a viable option for hospitals. Hospitals, therefore, are driven to pay higher prices to obtain da Vinci service and (more frequent) EndoWrist replacements from Intuitive.

152. Intuitive denies the allegations in paragraph 152.

Paragraph 153: EndoWrists are the only instruments that are FDA-approved to work with the da Vinci. Within its Sales Agreements for the da Vinci, Intuitive ties the purchase or lease of the robot to for the purchase of EndoWrists. Thus, customers have no choice but to accept Intuitive's restrictive terms and supracompetitive prices for the replacement of EndoWrists. Similarly, because Intuitive ties the purchase or lease of the da Vinci to the purchase of a da Vinci service agreement requiring all servicing of the da Vinci be performed by Intuitive or its agents, customers thereby accept Intuitive's restrictive terms despite the supracompetitive pricing that flows from Intuitive's anticompetitive scheme.

153. Intuitive admits that EndoWrists used with da Vincis have received FDA clearance, but otherwise denies the allegations in the first sentence of paragraph 153. Intuitive denies the allegations in the second, third and fourth sentences of paragraph 153.

Paragraph 154: Intuitive's tying and exclusive dealing scheme ensures high recurring revenues because it causes Intuitive's customers to constantly purchase EndoWrist instruments after as few as ten uses at a significant and unnecessary cost, instead of having them serviced for prolonged use, and to have to pay Intuitive inflated recurring fees for da Vinci service.

154. Intuitive denies the allegations in paragraph 154.

Paragraph 155: Restore claims to (a) offer service of the da Vinci at effective rates of less than 50% of the effective rates offered by Intuitive, and (b) repair EndoWrists at least 25% on average below replacement rates offered by Intuitive. SIS claims that a hospital would save 55-70% by having its EndoWrists serviced by SIS rather than purchasing replacement EndoWrists from Intuitive. Similarly, Rebotix claims to provide significant savings to hospitals on EndoWrist expenses, while providing as much safety and efficacy as Intuitive. And according to Great Lakes, repairing EndoWrists could save hospitals more than \$100,000 per robot, per year.⁶¹ With a current installed base of approximately 3,720 da Vincis in the U.S., this suggests a total savings of at least \$372 million per year on EndoWrists alone if EndoWrists were repaired by IRCs instead of having to be replaced by Intuitive. Savings likely would be even greater, for both da Vinci service and EndoWrist repairs, through IRCs' realization of economies of scale if they were not stifled by Intuitive's scheme.

Footnote 61: <https://www.greatlakesrobotics.net/sales>

155. Intuitive denies the allegations in the first, second, third and fourth sentences of paragraph 155 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive admits that in its 10-K for the year ended December 31, 2020, Intuitive reported an installed base of 3,720 da Vincis in the United States, but otherwise denies the allegations in the fifth sentence of paragraph 155. Intuitive denies the allegations in the sixth sentence of paragraph 155.

Paragraph 156: In the but-for world, absent Intuitive's unlawful restraints, Intuitive would need to compete on price to protect an erosion of its market share in response to IRCs' lower prices. For da Vinci service, this would mean lowering the prices charged by Intuitive for such service. For EndoWrists, this would mean reducing Intuitive's own prices for replacement EndoWrists, increasing the number of times an EndoWrist can be used, or both. The downward pressure on price that would result from unfettered competition between Intuitive and its IRC rivals would inure to the benefit of all direct purchasers in the market, whether they purchased from Intuitive or an IRC rival (or both).

156. Intuitive denies the allegations in paragraph 156.

Paragraph 157: According to a systematic cost assessment made on robotics in general surgery: “Nowadays, the only commercially available robotic equipment (da Vinci®, Intuitive Surgical Inc.; CA, USA) is characterized by elevated cost, including the cost of acquisition, training, and equipment-instrument cost, as well as that of maintenance of the robotic system (with an annual service contract, over 100,000 US dollars).”⁶²

Footnote 62: Gkegkes, I. D., Mamais, I. A., & Iavazzo, C. (2017). Robotics in General Surgery: A Systematic Cost Assessment. *Journal of Minimal Access Surgery*, 13(4), 243-255. <https://doi.org/10.4103/0972-9941.195565>

157. Intuitive denies the allegations in paragraph 157, except states that to the extent paragraph 157 purports to characterize and quote from a 2017 Robotics in General Surgery article, Intuitive respectfully refers to that article for its full context and contents.

Paragraph 158: By tying the purchase or lease of the da Vinci to both the service of the da Vinci and the commitment to purchase replacement EndoWrists from Intuitive rather than servicing already-owned EndoWrists, Intuitive captures nearly 100% of the U.S. da Vinci service aftermarket and EndoWrist Repair and Replacement Aftermarket. In its annual reports, Intuitive repeatedly notes that IRCs may emerge and compete with Intuitive on price or offerings, and Intuitive’s failure to compete successfully with these IRCs may cause its revenues to suffer. This acknowledgement from Intuitive demonstrates that absent Intuitive’s anticompetitive conduct, not only would the hospitals that purchased or leased da Vincis from Intuitive have cheaper alternatives from IRCs in terms of servicing the da Vinci and/or EndoWrists, but Intuitive would charge lower prices (and/or, with respect to EndoWrists, increase the maximum number of uses allowed) to better compete with these IRCs.

158. Intuitive denies the allegations in paragraph 158.

Paragraph 159: The exclusionary scheme has the effect of driving the majority of Intuitive’s annual revenues. First, demand for da Vinci service and EndoWrist replacement or repair is largely derived from demand for da Vincis. So, by purchasing a da Vinci to attract more patients and skilled surgeons to their facilities, hospitals are automatically locked into the Intuitive-controlled da Vinci service aftermarket and EndoWrist Repair and Replacement Aftermarket.

159. Intuitive denies the allegations in paragraph 159.

Paragraph 160: In fact, in its 2019 10-K, Intuitive reported 57% of its U.S. revenue was attributable to instruments and accessories, and 16% was attributable to service contracts.⁶³ In the U.S., Intuitive reported (a) \$508 million in revenue from service contracts, and (b) \$1.79 billion in revenue from instruments and accessories.⁶⁴ Furthermore, Intuitive’s net income for 2019 in the U.S. was 31% of total revenue.⁶⁵ This greatly exceeds the average profit margin of 8.5% in the medical equipment repair & maintenance industry.⁶⁶

Footnote 63: Intuitive (Form 10-K), at 56 (Feb. 7, 2020).

Footnote 64: *Id.* at 87.

Footnote 65: Id. at 45.

Footnote 66: Jack Curran, “Medical Equipment Repair & Maintenance Services,” IBIS World, June 2020, at 7.

160. Intuitive admits that in its 10-K for the year ended December 31, 2019, Intuitive reported total United States revenues of approximately \$3.13 billion, of which approximately 16% was attributable to service and approximately 57% was attributable to sales of instruments and accessories, but otherwise denies the allegations in the first sentence of paragraph 160. Intuitive admits that in its 10-K for the year ended December 31, 2019, Intuitive reported \$508.4 million in revenues for services to its customers in the United States and reported \$1.79 billion in revenues for the sale of instruments and accessories in the United States. Intuitive admits that in its 10-K for the year ended December 31, 2019, its net margin was over 30% based on its total revenue of \$4,478.5 million, and its net income attributable to Intuitive Surgical, Inc. of \$1,381.8 million. Intuitive otherwise denies the allegations in the first, second and third sentences of paragraph 160, except states that to the extent paragraph 160 further characterizes and quotes from Intuitive’s 10-K for the year ended December 31, 2019, Intuitive respectfully refers to that filing for its full context and contents. Intuitive denies the allegations in the fourth sentence of paragraph 160 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein, except states that to the extent paragraph 160 purports to characterize from a June 2020 IBIS World article, Intuitive respectfully refers to that article for its full context and contents.

Paragraph 161: There are no legitimate business, safety, or efficiency justifications for Intuitive’s anticompetitive scheme, which was employed for the sole purpose of eliminating competition in the da Vinci service aftermarket and EndoWrist Repair and Replacement Aftermarket, thereby causing Plaintiffs and the Class to pay significantly more than they would have in a competitive market for these services.

161. Intuitive denies the allegations in paragraph 161.

Paragraph 162: Intuitive has engaged in a continuing scheme to monopolize the aftermarket for

da Vinci service and the EndoWrist Repair and Replacement Aftermarket. In doing so, Intuitive has committed continuing overt acts in furtherance of that scheme. These acts include tying the purchase or lease of a da Vinci robot to the purchase of da Vinci service from Intuitive; tying da Vinci parts to the purchase of da Vinci service from Intuitive; requiring customers to enter into multi-year, exclusive da Vinci service agreements with Intuitive; designing the da Vinci to work only with parts with Intuitive serial numbers and refusing to provide such serial numbers to any third parties; restricting access to software necessary to maintain the da Vinci; tying the purchase or lease of a da Vinci to the commitment to abide by EndoWrist use limits and to purchase replacement EndoWrists from Intuitive once those limits are reached; tying the ongoing maintenance of the da Vinci to the commitment to abide by EndoWrist use limits and to purchase replacement EndoWrists from Intuitive once those limits are reached; requiring da Vinci purchasers not to repair their EndoWrists through IRCs; selling replacement EndoWrists with use-limit-triggered memory-wipers and at prices inflated by the scheme; forcing obsolescence of the S and Si da Vinci models and designing Xi and X model EndoWrists to thwart the use counter reset workarounds developed by IRCs; threatening and coercing IRCs such as SIS, Restore, and Rebotix; and threatening and coercing hospitals and other da Vinci robot purchasers who have expressed an interest in using IRCs to repair da Vinci robots or EndoWrists or using EndoWrists longer than the use limits arbitrarily set by Intuitive.

162. Intuitive denies the allegations in paragraph 162.

RESPONSE TO “CLASS ALLEGATIONS”

Paragraph 163: Plaintiffs bring this action on behalf of themselves and on behalf of a class (the “Class”) consisting of all entities that purchased da Vinci service and/or EndoWrists from Intuitive in the United States at any time from May 21, 2017 to the present (the “Class Period”). Excluded from the Class are Defendant, its officers, subsidiaries, and affiliates, and all government entities.

163. Intuitive admits that Plaintiffs bring this action on behalf of themselves and a purported Class, but otherwise denies the allegations in paragraph 163.

Paragraph 164: Plaintiffs seek class certification pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure.

164. Intuitive admits that Plaintiffs seek class certification pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure.

Paragraph 165: Numerosity. Hundreds of hospitals, trauma centers, and/or clinics have purchased da Vinci service and EndoWrists during the Class Period pursuant to Intuitive contracts that tied the purchase or lease of da Vincis to aftermarket sales of service and EndoWrist replacements (and also tied da Vinci service to EndoWrist replacements). Thus, there are numerous Class members and joinder is impracticable. The Class members are identifiable from information and records that are required by law to be maintained by Defendant.

165. Intuitive denies the allegations in paragraph 165.

Paragraph 166: Typicality. Plaintiffs' claims are typical of the claims of the other members of the proposed Class. Plaintiffs and members of the proposed Class purchased da Vinci service and/or EndoWrist replacements directly from Defendant during the Class Period at supracompetitive prices resulting from Defendant's unlawful actions. Plaintiffs and members of the Class have sustained damages in that they paid inflated prices for the service and repair of da Vincis and replacement of EndoWrists during the Class Period due to Defendant's conduct in violation of federal law.

166. Intuitive denies the allegations in paragraph 166.

Paragraph 167: Adequacy of Representation. Plaintiffs will fairly and adequately protect and represent the interests of the proposed Class. The interests of the Plaintiffs are not antagonistic to those of the proposed Class. In addition, Plaintiffs are represented by counsel who are experienced and competent in the prosecution of complex class action, antitrust, and consumer protection litigation.

167. Intuitive denies the allegations in the first and second sentences of paragraph 167.

Intuitive denies the allegations in third sentence of paragraph 167 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 168: Ascertainability. Plaintiffs have defined the Class so that Class members can be identified using objective criteria, i.e., entities that purchased da Vinci service and/or EndoWrists directly from Intuitive during the Class Period. Defendant's data can identify all Class members.

168. Intuitive denies the allegations in paragraph 168.

Paragraph 169: Commonality and Predominance. Questions of law and fact common to the members of the class predominate over questions, if any, that may affect only individual members.

169. Intuitive denies the allegations in paragraph 169.

Paragraph 170: Questions of law and fact common to the Class include without limitation:

- i. Whether Defendant's conduct constitutes illegal tying under Section 1 of the Sherman Act;
- ii. Whether Defendant's conduct constitutes illegal exclusive dealing under: Section 1 of the Sherman Act;
- iii. Whether Defendant's conduct constitutes illegal monopolization under Section 2 of the Sherman Act;
- iv. Whether Defendant abused its monopoly power in the U.S. minimally invasive surgical robot market in order to gain a competitive advantage in the aftermarkets to service and repair da Vincis and repair or replace

EndoWrists in violation of Sections 1 and 2 of the Sherman Act;
v. Whether Defendant's conduct had the effect of substantially lessening competition in the (1) da Vinci Service; and (2) EndoWrist Repair and Replacement Aftermarkets;
vi. Whether Defendant's unlawful conduct caused Plaintiffs and the proposed Class to pay more (1) for da Vinci service, and (2) to service, repair, and/or replace EndoWrists than they otherwise would have paid;
vii. The appropriate measure of damages incurred by Plaintiffs and the proposed Class;
viii. Whether Plaintiffs and other Class members are entitled to injunctive relief; and
ix. The appropriate injunction needed to restore competition in the aftermarkets.

170. Intuitive denies the allegations in paragraph 170.

Paragraph 171: Superiority. A class action is superior to other available methods for the fair and efficient adjudication of this controversy because joinder of all Class members is impracticable. The prosecution of separate actions by individual members of the Class would impose heavy burdens upon the courts and Defendant, and would create a risk of inconsistent or varying adjudications of the questions of law and fact common to the Class. A class action, on the other hand, would achieve substantial economies of time, effort, and expense, and would assure uniformity of decision as to persons similarly situated without sacrificing procedural fairness or bringing about other undesirable results.

171. Intuitive denies the allegations in paragraph 171.

Paragraph 172: The interest of members of the Class in individually controlling the prosecution of separate actions is theoretical rather than practical. The Class has a high degree of cohesion, and prosecution of the action through a representative or representatives would be unobjectionable. The amounts at stake for Class members, while substantial in the aggregate, are not great enough individually to enable them to maintain separate suits against Defendant. Plaintiffs do not anticipate any difficulty in the management of this action as a class action.

172. Intuitive denies the allegations in paragraph 172.

RESPONSE TO "CAUSES OF ACTION"

RESPONSE TO "COUNT I – TYING (DA VINCI SERVICE AFTERMARKET)"

Paragraph 173: Plaintiffs incorporate and reallege Paragraphs 1 through 172 of this Complaint as though fully set forth herein.

173. To the extent Plaintiffs re-allege all of the paragraphs above, Intuitive reasserts its answers to those paragraphs.

Paragraph 174: Intuitive has engaged in an unlawful tying arrangement in unreasonable

restraint of trade and commerce, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. This illegal scheme tied the purchase or lease of the da Vinci to da Vinci service.

174. Intuitive denies the allegations in paragraph 174.

Paragraph 175: Minimally invasive surgical robots and da Vinci service are separate products that are sold or leased in separate markets from one another.

175. Intuitive denies the allegations in paragraph 175.

Paragraph 176: At all times relevant to this action, Intuitive has maintained substantial economic power in the minimally invasive surgical robot market. Intuitive's tying arrangement has had anticompetitive effects in the domestic da Vinci service aftermarket.

176. Intuitive denies the allegations in paragraph 176.

Paragraph 177: Intuitive's tying scheme had no legitimate safety, efficiency, or business purpose. It achieved no legitimate efficiency benefits and had the anticompetitive effect of foreclosing competition in the aftermarket to service the da Vinci, such that Plaintiffs and the Class could obtain these services only from Intuitive.

177. Intuitive denies the allegations in paragraph 177.

Paragraph 178: A substantial amount of interstate commerce was affected by Intuitive's tying scheme. Intuitive reported \$508.4 million revenues from service contracts and \$1.79 billion revenues from instruments and accessories in 2019 alone. These amounts accounted for 73% of Intuitive's U.S. revenues in 2019.

178. Intuitive denies the allegations in the first sentence of paragraph 178. Intuitive admits that in its 10-K for the year ended December 31, 2019, Intuitive reported \$508.4 million in revenues for services to its customers in the United States and reported \$1.79 billion in revenues for the sale of instruments and accessories in the United States, and admits that the reported revenues from services to its customers and sales of instruments and accessories in the United States accounted for approximately 73% of Intuitive's United States revenues in the year ended December 31, 2019, but otherwise denies the allegations in the second and third sentences of paragraph 178.

Paragraph 179: As a direct and proximate result of the foregoing conduct, Intuitive has caused customers to purchase da Vinci service at supracompetitive prices. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the

Sherman Act.

179. Intuitive denies the allegations in paragraph 179.

RESPONSE TO “COUNT II – EXCLUSIVE DEALING (DA VINCI SERVICE AFTERMARKET)”

Paragraph 180: Plaintiffs incorporate and reallege Paragraphs 1 through 172 of this Complaint as though fully set forth herein.

180. To the extent Plaintiffs re-allege all of the paragraphs above, Intuitive reasserts its answers to those paragraphs.

Paragraph 181: Intuitive has dominant economic power in the domestic market for minimally invasive surgical robots, the domestic da Vinci service aftermarket, and the domestic EndoWrist Repair and Replacement Aftermarket. Intuitive has taken measures and entered into agreements with its customers that require the customers to purchase service for the da Vinci from Intuitive exclusively. These agreements are unreasonable restraints of trade that have foreclosed competition in the domestic da Vinci service aftermarket, in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2.

181. Intuitive denies the allegations in paragraph 181.

Paragraph 182: As a direct and proximate result of the foregoing conduct, Intuitive has caused customers to purchase da Vinci service at supracompetitive prices. These injuries are antitrust injuries, because they flow from that which makes Intuitive’s conduct unlawful under the Sherman Act.

182. Intuitive denies the allegations in paragraph 182.

RESPONSE TO “COUNT III – MONOPOLIZATION (DA VINCI SERVICE AFTERMARKET)”

Paragraph 183: Plaintiffs incorporate and reallege Paragraphs 1 through 172 of this Complaint as though fully set forth herein.

183. To the extent Plaintiffs re-allege all of the paragraphs above, Intuitive reasserts its answers to those paragraphs.

Paragraph 184: Intuitive has willfully obtained and willfully maintains monopoly power in the domestic da Vinci service aftermarket in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Intuitive maintains at least a 98% market share by excluding competitors. Intuitive’s exclusionary tactics include tying the purchase or lease of the da Vinci to the purchase of service from Intuitive; including contractual provisions in sales and servicing agreements prohibiting customers from having their da Vincis serviced by third parties; designing da Vincis to inhibit

the ability of IRCs to perform maintenance on them; sending cease-and-desist letters when customers attempt to use IRCs to service da Vincis; and threatening customers who attempt to repair their da Vincis with IRCs.

184. Intuitive denies the allegations in paragraph 184.

Paragraph 185: As a direct and proximate result of the foregoing conduct, Intuitive has caused customers to purchase da Vinci service at supracompetitive prices. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

185. Intuitive denies the allegations in paragraph 185.

RESPONSE TO "COUNT IV – TYING (ENDOWRIST REPAIR AND REPLACEMENT AFTERMARKET)"

Paragraph 186: Plaintiffs incorporate and reallege Paragraphs 1 through 172 of this Complaint as though fully set forth herein.

186. To the extent Plaintiffs re-allege all of the paragraphs above, Intuitive reasserts its answers to those paragraphs.

Paragraph 187: Intuitive has dominant economic power in the domestic market for minimally invasive surgical robots. Intuitive has tied the purchase or lease of the da Vinci and purchase of da Vinci service to customers purchasing replacement EndoWrists from Intuitive instead of repairing the EndoWrists that the customers already have, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

187. Intuitive denies the allegations in paragraph 187.

Paragraph 188: Minimally invasive surgical robots and the service, repair, and replacement of EndoWrists are separate products that are sold or leased in separate markets from one another.

188. Intuitive denies the allegations in paragraph 188.

Paragraph 189: Intuitive's tying scheme had no legitimate safety, efficiency, or business purpose. It achieved no legitimate efficiency benefits and had the anticompetitive effect of foreclosing competition in the market to service, repair, and replace EndoWrists such that Plaintiffs and the Class could obtain these services only from Intuitive.

189. Intuitive denies the allegations in paragraph 189.

Paragraph 190: A substantial amount of interstate commerce was affected by Intuitive's tying scheme. Just in 2019, Intuitive's total revenues from instruments and accessories, including EndoWrists, exceeded \$1.79 billion, and Intuitive reported \$508 million revenues from service contracts. These amounts accounted for 73% of Intuitive's U.S. revenues in 2019.

190. Intuitive denies the allegations in the first sentence of paragraph 190. Intuitive admits that in its 10-K for the year ended December 31, 2019, Intuitive reported \$508.4 million in revenues for services to its customers in the United States and reported \$1.79 billion in revenues for the sale of instruments and accessories in the United States, and admits that the reported revenues from services to its customers and sales of instruments and accessories in the United States accounted for approximately 73% of Intuitive's United States revenues in the year ended December 31, 2019, but otherwise denies the allegations in the second and third sentences of paragraph 190.

Paragraph 191: As a direct and proximate result of the foregoing conduct, Intuitive has caused customers to purchase EndoWrists unnecessarily at supracompetitive prices. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

191. Intuitive denies the allegations in paragraph 191.

RESPONSE TO "COUNT V – EXCLUSIVE DEALING (ENDOWRIST REPAIR AND REPLACEMENT AFTERMARKET)"

Paragraph 192: Plaintiffs incorporate and reallege Paragraphs 1 through 172 of this Complaint as though fully set forth herein.

192. To the extent Plaintiffs re-allege all of the paragraphs above, Intuitive reasserts its answers to those paragraphs.

Paragraph 193: Intuitive has dominant economic power in the domestic market for minimally invasive surgical robots, the domestic da Vinci service aftermarket, and the domestic EndoWrist Repair and Replacement Aftermarket. Intuitive has taken measures and entered into agreements with its customers that require the customers to service and replace their EndoWrist instruments with Intuitive exclusively. These agreements are unreasonable restraints of trade that have foreclosed competition in the domestic EndoWrist Repair and Replacement Aftermarket, in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2.

193. Intuitive denies the allegations in paragraph 193.

Paragraph 194: As a direct and proximate result of the foregoing conduct, Intuitive has caused customers to purchase EndoWrists unnecessarily at supracompetitive prices. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

194. Intuitive denies the allegations in paragraph 194.

**RESPONSE TO “COUNT VI – MONOPOLIZATION
(ENDOWRIST REPAIR AND REPLACEMENT AFTERMARKET)”**

Paragraph 195: Plaintiffs incorporate and reallege Paragraphs 1 through 172 of this Complaint as though fully set forth herein.

195. To the extent Plaintiffs re-allege all of the paragraphs above, Intuitive reasserts its answers to those paragraphs.

Paragraph 196: Intuitive has willfully obtained and willfully maintains monopoly power in the domestic EndoWrist Repair and Replacement Aftermarket in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Intuitive maintains at least a 98% market share by excluding competitors. Intuitive’s exclusionary tactics include tying the purchase or lease of da Vincis to the commitment to abide by EndoWrist use limits and to purchase replacement EndoWrists from Intuitive once those limits are reached, tying the ongoing maintenance of da Vincis to the commitment to abide by EndoWrist use limits and to purchase replacement EndoWrists from Intuitive once those limits are reached, prohibiting customers from having their EndoWrists repaired, sending cease-and-desist letters when customers attempt to repair EndoWrists, threatening customers who attempt to repair EndoWrists, incorporating a memory-wiper into every EndoWrist to require additional EndoWrist purchases instead of repairs, and introducing design changes intended to thwart repair solutions developed by IRCs in response to the memory-wiper.

196. Intuitive denies the allegations in paragraph 196.

Paragraph 197: As a direct and proximate result of the foregoing conduct, Intuitive has caused customers to purchase EndoWrists unnecessarily at supracompetitive prices. These injuries are antitrust injuries, because they flow from that which makes Intuitive’s conduct unlawful under the Sherman Act.

197. Intuitive denies the allegations in paragraph 197.

RESPONSE TO “PRAYER FOR RELIEF”

Responding to the unnumbered paragraph and each of its subparts under the heading “PRAYER FOR RELIEF,” Intuitive denies that Plaintiffs are entitled to certification of any class, any damages, pre- or post-judgment interest, costs of suit, attorney’s fees, injunctive relief, declaratory relief or any other form of relief.

RESPONSE TO “JURY DEMAND”

Intuitive admits that Plaintiffs, on behalf of themselves and the purported Class, demand trial of all claims by jury to the extent authorized by law.

PREAMBLE TO AFFIRMATIVE DEFENSE

Intuitive reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial and thus reserves the right to amend its Answer and Affirmative Defense. By asserting the following affirmative defense, Intuitive does not allege or admit it has the burden of proof or the burden of persuasion with respect to any matter:

FIRST DEFENSE

Plaintiffs’ claims are barred, in whole or in part, by the applicable statute of limitations.

DATED: January 18, 2022

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